EPA Reg. No. 499-568

Inert ingredient information may be entitled to confidential treatment

Benbow, Gene

From: Kerry Dawson Sosa <kerry.sosa@basf.com>
Sent: Wednesday, October 10, 2018 9:23 AM
To: Benbow, Gene; Jonathan D Berger
Subject: RE: 499-568

Thank you so much Gene! Our operations team will be very excited that we can now transition this product to the new manufacturing site and begin production again.

Also, I really appreciate your discretion in the review of the changes made to the CSF. I will be sure to pass along the information you provided below to my technical team. Our regulatory group has been working closely with our technical team since you and I spoke in July regarding the CSF changes for EPA Reg. No. 499-294 to make sure everyone is aware of the EPA requirements for changes to bait products.

Best Regards,
Kerry Sosa
Product Registration Manager, Professional & Specialty Solutions

Phone: +1 (919) 547-2193, Mobile: +1 (919) 433-7397, Email: kerry.sosa@basf.com
Postal Address: BASF Corporation, Agricultural Solutions, 26 Davis Drive, Research Triangle Park, NC 27709-3528, USA

We create chemistry

BASF Corporation

From: Benbow, Gene <Benbow.Gene@epa.gov>
Sent: Wednesday, October 10, 2018 8:50 AM
To: Jonathan D Berger <jonathan.berger@basf.com>; Kerry Dawson Sosa <kerry.sosa@basf.com>
Subject: FW: 499-568

Hi Jonathan/Kerry,

The new proposed Basic CSF contains a very slight change to one ingredient, and a swap of another ingredient entirely [redacted]. Since this is a pesticide bait product, any changes to the formulation that could affect bait acceptance can trigger the requirement to conduct and submit new efficacy data (or a palatability test per what I'm told by the PERC).

I have approved this new Basic CSF based upon my best judgement and also because I realize that you guys are in a bind and have been waiting for this action for a very long time now. **It is entirely possible that these or similar changes to a CSF for another of your bait products may result in you being asked for efficacy data.** I just wanted to let you know about this ahead of time in case you run into it down the road.

I will be working on your associated 7969-397 action as soon as I can --

Regards,

Gene Benbow

Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division
703-347-0235

From: VA-PYS-7251-M@epa.gov [mailto:VA-PYS-7251-M@epa.gov]
Sent: Wednesday, October 10, 2018 8:23 AM
To: Benbow, Gene <Benbow.Gene@epa.gov>
Subject:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 10, 2018

Kerry Sosa
BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

Subject: CSF Amendment – Replace all of the currently approved CSFs with a new Basic CSF
Product Name: PT Alpine Pressurized Fly Bait
EPA Registration Number: 499-568
Application Date: December 6, 2017
Decision Number: 538205

Dear Ms. Sosa:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 10/05/18

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Gene Benbow by phone at 703-347-0235, or via email at Benbow.Gene@epa.gov.

Sincerely,

Gene Benbow, Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

BASF

We create chemistry

December 06, 2017

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard (South Building)
2777 South Crystal Drive
Document Processing Desk, Room S-4900
Washington, DC 22202-4501

Attention: Mr. Gene Benbow – PM 7

Dear Mr. Benbow:

SUBJECT: Registration Amendment to Replace All Current Confidential Statements of Formula for PT® Alpine® Pressurized Fly Bait (EPA Reg. No. 499-568)

BASF Corporation is submitting this registration amendment to the EPA to replace Confidential Statements of Formula (CSF) on file for **PT® Alpine® Pressurized Fly Bait (EPA Reg. No. 499-568)** with a new Basic CSF dated November 20, 2017. This proposed Basic CSF dated November 20, 2017 will replace all current CSFs on file with the Agency.

The following documents are included with this submission:

1. Completed EPA Form 8570-1 "Application for Pesticide";
2. Revised Basic Confidential Statement of Formula dated November 20, 2017; and
3. Completed EPA Form 8570-27 "Formulator's Exemption Statement".

BASF considers this a registration amendment that qualifies for a "fast track" expedited review and is not a PRIA action. Therefore, BASF is not proposing any PRIA Category because none is triggered, and no PRIA fee is associated with this proposed amendment. This information has also been included in Section II of the EPA Form 8570-1 "Application for Pesticide."

Thank you for your attention to this action. If you have any questions or need clarification or further information, I can be reached directly by phone at (919) 547-2193, or by e-mail at kerry.sosa@basf.com.

Sincerely,

Kerry Sosa
Product Registration Manager, Regulatory Affairs
BASF Corporation

Enclosures

Alpine® and **PT®** are registered trademarks of BASF

BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709-3528
Tel: (919) 547-2000
www.basf.com/usa

Please read instructions on reverse before comple, form. Form Approved. 3 No. 2070-0060. Approval expires 2-28-95

United States
Environmental Protection Agency
Washington, DC 20460

- [ ] Registration
- [x] Amendment
- [ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
BASF Corporation EPA Reg. No. 499-568	Gene Benbow	[x] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
BASF Corp./PT® Alpine® Pressurized Fly Bait	7	

5. Name and Address of Applicant *(Include ZIP Code)*

BASF Corporation
P.O. Box 13528 26 Davis Drive
Research Triangle Park, NC 27709

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

- [x] Amendment - Explain below.
- [ ] Resubmission in response to Agency letter dated _____
- [ ] Notification - Explain below.
- [ ] Final printed labels in repsonse to Agency letter dated _____
- [ ] "Me Too" Application.
- [ ] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of registration amendment to replace all CSFs on file with the Agency with 1 Basic CSF dated 11/20/2017 for PT® Alpine® Pressurized Fly Bait (EPA Reg. No. 499-568). See cover letter for supporting details. BASF considers this a registration amendment that qualifies for a "fast track" expedited review and is not a PRIA action. Therefore, BASF is not proposing any PRIA Category because none is triggered, and no PRIA fee is associated with this proposed amendment. If you have any questions, I can be reached by e-mail or phone. E-Mail: kerry.sosa@basf.com/Phone: 919-547-2193

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
Certification must be submitted	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

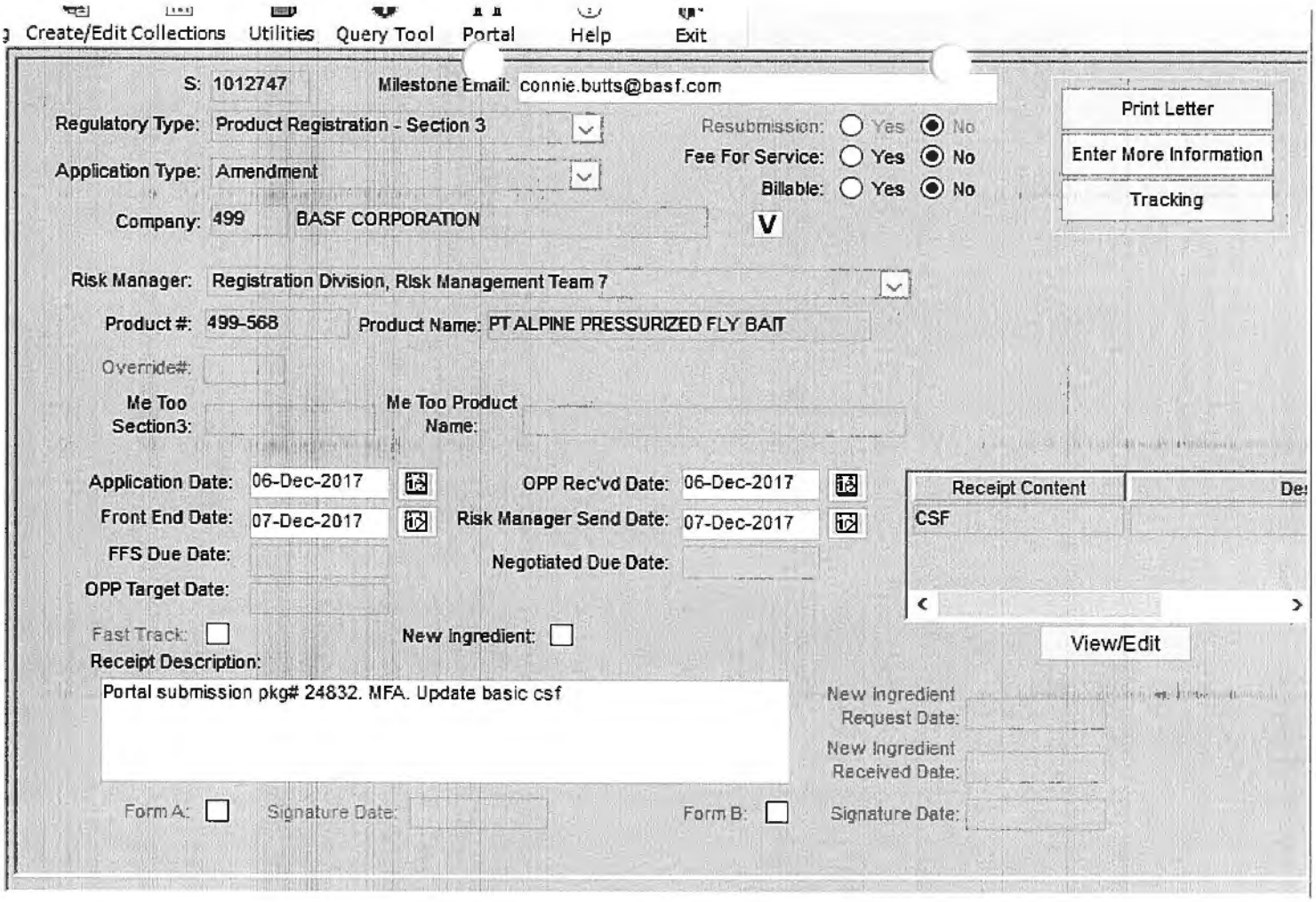
Name	Title	Telephone No. (Include Area Code)
Kerry Sosa	Product Registration Manager	(919) 547-2193

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title
Kerry Sosa	Product Registration Manager, Regulatory Affairs
4. Typed Name	**5. Date**
Kerry Sosa	December 06, 2017


Create/Edit Collections
Utilities
Query Tool
Portal
Help
Exit
S: 1012747
Milestone Email: connie.butts@basf.com
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 499 BASF CORPORATION
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 499-568
Product Name: PT ALPINE PRESSURIZED FLY BAIT
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 06-Dec-2017
Front End Date: 07-Dec-2017
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 06-Dec-2017
Risk Manager Send Date: 07-Dec-2017
Negotiated Due Date:
Receipt Content
CSF
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Portal submission pkg# 24832. MFA. Update basic csf
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

FAST-TRACK AMENDMENTS – Completeness Screening Checklist

N/F

Expert's In-Processing Signature: Heather Sievers Date: 12/6/17 PM #: 7

EPA Reg. Number: 499-568 EPA Receipt Date: 12/6/17

	Checklist Item	Yes	No	N/A
1	**Application Form** (EPA Form 8570-1) - signed?	✓		
2	**Confidential Statement of Formula** (EPA Form 8570-29) - signed?	✓		
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) - signed?		✓	
4	**Formulator's Exemption Statement** (EPA Form 8570-27) - signed?	✓		
5	**Data Matrix** (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?		✓	
	a) Selective Method?			
	b) Cite-All Method?			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	**Is Label included?** (5 copies)		✓	
	a) Electronic Label submitted?			

Comments:

Replace CSF on file with a new basic CSF.

Inerts not approved. See status form attached to the CSF. D. Debosier 2.6.18.

Dic

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

December 7, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MS. CHRISTINE KEATING
BASF CORPORATION
26 DAVIS DRIVE, PO Box 13528
RESEARCH TRIANGLE PARK, NC 27709-3528

PRODUCT NAME: PT ALPINE PRESSURIZED FLY BAIT
COMPANY NAME: BASF CORPORATION
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 499-568
EPA RECEIPT DATE: 12/06/17

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 7, at (703) 305-0120.

Sincerely,

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service {1012747U~

This package includes the following

- ○ New Registration
- ◉ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S-	1012747
EPA File Symbol/Reg. No.	499-568
Pin-Punch Date:	12/6/2017

☑ This item is NOT subject to FFS action.

Action Code:

Requested: ____

Granted: ____

Amount Due: $ _____

Parent/Child Decisions:

A. Debesai 2-6-18

☐ Inert Cleared for Intended Use ☒ Uncleared Inert in Product

Reviewer: Alan Jan Date: 12/7/17

Remarks: OSF amendment 345

* Inerts *

Form approved. OMB No. 2070-0060, 2070-0057, 20. ,107, 2070-0122, 2070-0164.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
BASF Corporation 26 Davis Dr. Research Triangle Park, NC 27709	499-568
	Product Name PT® Alpine® Pressurized Fly Bait
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 11/20/2017

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Dinotefuran; CAS # 165252-70-0

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☑ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Dinotefuran	[redacted]	
Signature	Name and Title	Date
	Kerry Sosa, Registration Manager	12/06/2017

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OFCHEMICAL
SAFETY AND POLLUTION
PREVENTION

October 1, 2015

I, Mark Suarez, Invertebrate and Vertebrate Branch 3, Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, United States Environmental Protection Agency ("EPA"), certify that the pesticide product (s) listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product(s) may be sold and marketed in the United States of America as authorized and limited by FIFRA. A true and correct copy of the product label approved by EPA is attached to accompany this letter.

Registration of this product(s) with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all the laws of the United States of America, or governing jurisdiction, regarding the sale, storage and/or disposal of the product(s). Further, the recipient of this letter is on notice that the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient(s) (i.e., Taiwan) of this letter of any change in the status of the registration(s) and/or the product label for the product(s) listed below.

EPA has issued registration numbers for the product(s) listed below to:

BASF Corporation
26 Davis Drive
P. O. Box 13528
Research Triangle Park, NC 27709

EPA Registration Number: 499-568
Name of Product: PT ALPINE PRESSURIZED FLY BAIT

Mark Suarez
Risk Manager 07
Invertebrate and Vertebrate Branch 3
Registration Division (7505P)

Crop Protection

BASF

We create chemistry

150 years

September 23, 2015

~~Richard J. Gebken~~ MARK SUNREL
Product Manager ~~(#10)~~ 7
Insecticide Branch, Registration Division (7504P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

Re: Request for GOLD SEAL Letter of Certification for PT® Alpine® Pressurized Fly Bait Insecticide (EPA Reg. No. 499-568) for the Country of Taiwan

Dear Mr. Gebken:

To support international registrations, BASF Corporation is urgently requesting **one (1)** Gold Seal letter for **Taiwan** indicating that **PT® Alpine® Pressurized Fly Bait Insecticide** (EPA Reg. No. 499-568) is registered in the United States. I would appreciate it if the Gold Seal letter included the following statement: **the product may be sold and marketed in the United States of America.**

As proof of registration, I have attached the most current stamped-approved label for **PT® Alpine® Pressurized Fly Bait Insecticide.**

Please note: The company name and address on the Gold Seal Letter should be as listed below. Please forward the letters to the attention of Paulette Tabor-Brown.

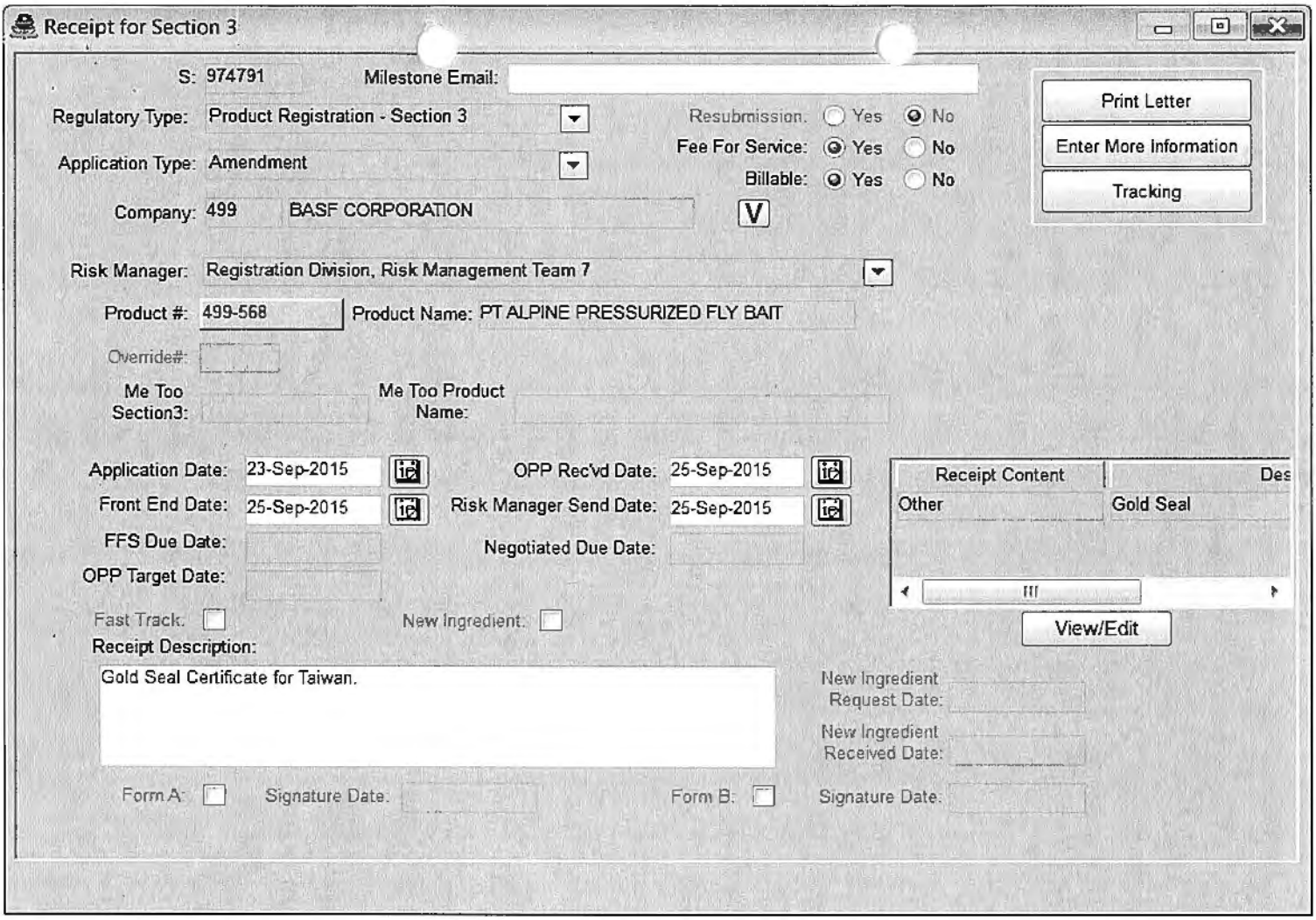
BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

Thank you for your prompt response to this request. Should you have any questions, I may be reached at (919) 547-2282.

Sincerely,
BASF Corporation
Crop Protection

Amy Dugger-Webster
Amy Dugger-Webster,
Global Registration Manager
ADW/ptb
Encl.

BASF Corporation
26 Davis Drive
PO Box 13528
Research Triangle Park NC 27709-3528
Tel (919) 547-2000
Web Site: www.basf.com/usa


Receipt for Section 3
S: 974791
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: Amendment
Company: 499 BASF CORPORATION
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 7
Product #: 499-568
Product Name: PT ALPINE PRESSURIZED FLY BAIT
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 23-Sep-2015
Front End Date: 25-Sep-2015
FFS Due Date:
OPP Target Date:
OPP Rec'vd Date: 25-Sep-2015
Risk Manager Send Date: 25-Sep-2015
Negotiated Due Date:
Receipt Content
Des
Other
Gold Seal
View/Edit
Fast Track:
New Ingredient:
Receipt Description:
Gold Seal Certificate for Taiwan.
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

September 25, 2015

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-509454
EPA File Symbol or Registration Number: 499-568
Product Name: PT ALPINE PRESSURIZED FLY BAIT
EPA Receipt Date: 25-Sep-2015
EPA Company Number: 499
Company Name: BASF CORPORATION

PAULETTE TABOR-BROWN
BASF CORPORATION
26 DAVIS DRIVE, PO Box 13528
RESEARCH TRIANGLE PARK, NC 27709-

SUBJECT: Receipt of Request for Gold Seal Certification Letter(s)

Dear Registrant:

The Office of Pesticide Programs has received your request for Gold Seal Certification letter(s) that is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The action has been identified as action code M006:

UP TO 5 GOLD SEAL CERTIFICATION LETTERS PER REGISTRATION

No additional payment is due at this time. If you have any questions, please contact Betty Williams at (703) 308-0132.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[ ] Registration
[ ] Amendment
[X] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
BASF Corporation / 499-568	Richard Gebken	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
BASF Corporation / PT® Alpine® Pressurized Fly Bait Insecticide	Team 10	

5. Name and Address of Applicant *(Include ZIP Code)*

BASF Corporation
26 Davis Drive, PO Box 13528
Research Triangle Park, NC 27709

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in reponse to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

MISCELLANEOUS ACTION: Submission of a request for Gold Seal letters of certification for the EPA-registered product "PT® Alpine® Pressurized Fly Bait Insecticide.

This submission pertains to PRIA code M006, Request for up to 5 letters of certification (Gold Seal) for one actively registered product, with $263 fee and 1 month review.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Yes [ ] No	[ ] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt. / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[ ] Label [ ] Container		[ ]

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Amy Dugger-Webster	Global Registration Manager	(919) 547-2282

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title
Amy Dugger-Webster	Global Registration Manager
4. Typed Name	**5. Date**
Amy Dugger-Webster	September 23, 2015

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

BASF
The Chemical Company

Crop Protection

September 23, 2015

U.S. Environmental Protection Agency
Office of Pesticide Programs (7505P)
Document Processing Desk 7504P (**REGFEE**)
Room S-4900
One Potomac Yard (South Building)
2777 South Crystal Drive
Arlington, VA 22202 U.S.A.
Attention: Richard Gebken, Registration Div., Insecticide Branch – 7505P, PM Team 10

RE: REQUEST for GOLD SEAL Letter of Certification
PT® Alpine® Pressurized Fly Bait Insecticide (EPA Reg. No. 499-568)

Dear Mr. Gebken:

With this letter, BASF is requesting **(1) one** Gold Seal letter of certification for the EPA-registered product PT® Alpine® Pressurized Fly Bait Insecticide.

This request for a Gold Seal letter is submitted for EPA review as the following PRIA action:

PRIA code M006,
Request for up to 5 letters of certification (Gold Seal) for one actively registered product
1 month review, $263 fee.

The PRIA fee was paid **September 23, 2015** with BASF Corporation's corporate JP Morgan Master Card credit card.

Please see the attached sheet for acknowledgement and confirmation of fee payment, as:

Pay.gov Tracking ID No: **25NHESER**
Payment Agency Tracking ID No: **74878267572**

Regards,

Amy Dugger - Webster

Amy Dugger-Webster,
Regulatory Affairs
E-mail: amy.s.dugger-webster@basf.com
Tel: (919) 547-2282

ADW/ptb
Encl.

BASF Corporation
Crop Protection
26 Davis Drive, PO Box 13528
Research Triangle Park
NC 27709-3528
Tel: (919) 547-2000
www.basf.com/usa

® Registered Trademark of BASF

Paulette L Tabor-Brown

From: Robin N Payne
Sent: Wednesday, September 23, 2015 1:01 PM
To: Paulette L Tabor-Brown
Subject: FW: Pay.gov Payment Confirmation: PRIA Service Fees

Best regards,
Robin Payne
Administrative Assistant

Phone: +1 919 547-2865 Mobile: +1-919-812-1057 Fax: +1 919 547-2850 E-Mail: robin.payne@basf.com Postal Address: BASF Corporation, 26 Davis Drive, Research Triangle Park 27709, USA

150 years
BASF - We create chemistry

BASF Corporation
100 Park Avenue
Florham Park, NJ 07932
USA
-----Original Message-----
From: notification@pay.gov [mailto:notification@pay.gov]
Sent: Wednesday, September 23, 2015 1:00 PM
To: Robin N Payne <robin.payne@basf.com>
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or yanchulis.michael@epa.gov.

Application Name: PRIA Service Fees
Pay.gov Tracking ID: 25NHESER
Agency Tracking ID: 74878267572
Transaction Type: Sale
Transaction Date: 09/23/2015 01:00:16 PM EDT

Account Holder Name: John J Arthur

Transaction Amount: $263.00
Billing Address: BASF Corporation
Billing Address 2: 26 Davis Drive
City: Durham
State/Province: NC
Zip/Postal Code: 27709
Country: USA
Card Type: MasterCard
Card Number: **********8166

Registration Number: 499-568
Company Name: BASF Corporation
Company Number: 7969
Action Code: M006

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Kumar, Rita

From: Christine Keating <christine.keating@basf.com>
Sent: Tuesday, May 12, 2015 12:33 PM
To: Kumar, Rita
Subject: Re: FW: 499-568 ss and cc review
Attachments: image2015-05-12-112246.pdf

Hello Rita -

I have received the attachment. Thank you for sending this along.

Best Regards,
Christine Keating
Product Registration Manager
Professional & Specialty Solutions

Phone: +1 919 547-2697 Mobile: +1 919 928 1257 Fax: +1 919 547-2488 E-Mail: christine.keating@basf.com
Postal Address: BASF Corporation, 26 Davis Drive Research Triangle Park, NC 27709, USA

150 years
BASF - We create chemistry

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Christine Keating <christine.keating@basf.com>
Date: 05/12/2015 11:29 AM
Subject: FW: 499-568 ss and cc review

Dear Christine: Please see attached. This action is now complete.
Regards,
Rita

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MAY 12 2015

Ms. Christine Keating
Product Registration Manager
BASF Corporation
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122-6682

Dear Ms. Keating:

Subject: Conditional data: storage stability and corrosion characteristics
PT Alpine Pressurized Fly Bait
EPA File Symbol 499-568
Your submission dated Sept. April 25, 2014
OPP Decision Number D494405

The storage stability and corrosion characteristics study (MRID # 49369201) is acceptable, and these data requirements are now satisfied. We have added this information to our files for this product.

If you have any questions, contact me at (703) 308-8291, or kumar.rita@epa.gov.

Yours Sincerely,

Rita Kumar

Rita Kumar
Senior Regulatory Specialist
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DATE OUT: December 29, 2014

SUBJECT: **STORAGE STABILITY (830.6317) & CORROSION CHARACTERISTICS (830.6320) REVIEW**
ACCELERATED STUDY [ ]; ONE YEAR STUDY [X];
OVER 1 YEAR STUDY [ ]
MP [ ] EP [X] EUP [ ]
DP BARCODE No.: 422385 **REG. No.:** 499-568 **FILE SYMBOL No.:**
DECISION No.: 494405 **MRID No(s):** 493692-01
PRODUCT NAME: PT ALPINE PRESSURIZED FLY BAIT
COMPANY: BASF CORPORATION

FROM: Linda Mascall / Bruce Kitchens Linda Mascall Bruce Kitchens 12/29/14
Product Chemistry Team
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/RD (7505P)

TO: Rita Kumar / Reuben Bairs, RM 07
Insecticide-Rodenticide Branch / RD (7505P)

I. CONCLUSIONS:

STORAGE STABILITY (830.6317):
[X] ACCEPTABLE
[ ] UNACCEPTABLE*
[ ] UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: [X] SATISFIED [ ] NOT SATISFIED

CORROSION CHARACTERISTICS (830.6320):
[X] ACCEPTABLE
[ ] UNACCEPTABLE*
[ ] UPGRADEABLE*

40CFR158.310 DATA REQUIREMENT: [X] SATISFIED [ ] NOT SATISFIED

* If unacceptable or upgradeable describe the deficiency and provide recommendations

Comments & Recommendations:

After twelve (12) months storage BAS 396 KC 1 (TC-333) active ingredient was stable at room temperature. BAS 395 KC 1 (TC-333) did not cause any adverse corrosive effects on the plastic laminate aerosol storage containers. Even with the slight flattening of the plastic laminate, there was neither plastic delamination nor corrosion to the underlying steel.

II. STUDY SUMMARY

A. STUDY CONDUCTED UNDER US GLP/OECD GUIDELINES

[X] Yes
[ ] No

B. PRODUCT INFORMATION

Active ingredient(s): Dinotefuran
Label claim(s) Nominal concentration(s) (%): 1.0
Initial concentration(s) of the AI(s) (%) used in the study: 0.9640
Lower certified limits (%) based on AI % in the study: 0.9036

C. EXPERIMENTAL PARAMETERS

Temperature: [ ] Freezer; Room [X]; Warehouse [ ]; 54°C [ ]; Other [ ]
Humidity: Indicate % (if provided)
Duration of study: [X] 1 year; [ ] over 1 year
Type of container: [ ] Glass; [ ] Metal; [ ] HDPE; [X] Fluorinated HDPE; [ ] Other
Analysis at intervals: [X] 0 (initial);
[X] 3 months; [X] 6 months
[X] 9 months; [X] 12 months
[ ] Over 12 months

D. ANALYTICAL METHOD

Method	DETECTOR
Gas chromatography (GC)	☐ FID (Flame Ionization Detector) ☐ ECD (Electron Capture Detector) ☐ N/P (Nitrogen/Phosphorous Detector) ☐ Other
Capillary Gas chromatography (CGC)	☐ FID (Flame Ionization Detector) ☐ ECD (Electron Capture Detector) ☐ N/P (Nitrogen/Phosphorous Detector) ☐ Other
High Pressure Liquid chromatography (HPLC)	√ UV/VIS (nm) - 225 nm ☐ RI (Refractive Index) ☐ Other
GC-MS / LC-MS	Specify
Other	Specify

E. RESULTS

Chemical and Physical Stability of BAS 395 KC 1 (TC-333)

Analysis Date	Interval (Days)	Days from Initial	Dinotefuran Analysis Result (Target 1.0000)%	3X ó	% Initial
October 22, 2012	0	0	0.9640	0.0241	-
January 31, 2013	101	101	0.9417	0.0523	98
April 29, 2013	88	189	0.9531	0.0113	99
August 15, 2013	108	297	0.9092	0.0097	94
November 1, 2013	76	375	1.0023	0.0042	104

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 05, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BASF CORPORATION
26 DAVIS DRIVE
RESEARCH TRIANGLE PARK, NC 27709

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 28-APR-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studes, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

49369201

* You must include one of the two acceptable statements of data confidentiality claims under FIFRA section10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See pages 8 and 13 of the Notice.

* Judging from the pagination of the study, pages____2, 4, 6, 8, 10____ were omitted from the submitted copy.

Corrected study has been uploaded to Documentum
Teresa Dorsey
5/29/14

BASF
The Chemical Company

49369200

April 25, 2014

Document Processing Desk (REGFEE)
OPP/IB/RD (7504P)
U.S. Environmental Protection Agency
ATTN: Mr. Reuben Baris, Acting PM 7
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Re: Submission of One-Year Storage Stability and Corrosion Characteristics Study Report
PT® Alpine® Pressurized Fly Bait, EPA Reg. No. 499-568

Dear Mr. Baris:

Submitted herein is the one-year storage stability and corrosion characteristics study report for PT® Alpine® Pressurized Fly Bait (aka TC-333, BAS 395 KC I) to satisfy the condition of registration from the February 18, 2014 Notice of Pesticide Registration. Enclosed in support of this action is the following documentation:

- Transmittal Document (with associated data)
- Application for Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)

My last day with BASF is May 2, 2014, so please contact Jenna Garwood at (919) 659-3930 or jenna.garwood@basf.com (see below for mailing address), should you have any questions or require additional information.

Sincerely,

Dana M. Thomas
Product Registration Mgr.

Encl.

Jenna Garwood
Product Registration Specialist
BASF Corporation
26 Davis Drive, P4107
Research Triangle Park, NC 27009
919-659-3930; jenna.garwood@basf.com

BASF Corporation
Pest Control Solutions
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122

TRANSMITTAL DOCUMENT

Applicant:
BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709
Submitter: Dana Thomas (Jenna Garwood)
Email: jenna.garwood@basf.com
Telephone: (919) 659-3930

Reason for Transmittal:
Submission of One-Year Storage Stability and Corrosion Characteristics Study Report
PT® Alpine® Pressurized Fly Bait
EPA Reg. No. 499-568

Date of Transmittal: April 25, 2014

Administrative Material Included in Submission:

1. Cover letter, dated June 12, 2013
2. Application (Form 8570-1)
3. Certification with Respect to Citation of Data (Form 8570-34)
4. Data Matrix (Form 8570-35)
   - ✓ Agency Internal Use Copy
   - ✓ Public File Copy

Studies Included in Submission:

Product Chemistry *(3 bound copies)*

- Storage Stability and Corrosion Characteristics of BAS 395 KC I (TC-333); Laboratory Project ID: 12-0652 [Note: TC-333 = PT® Alpine® Pressurized Fly Bait]

MRID No. **49369201**

Name: Dana M. Thomas **Signature:** Dana M Thomas

Title: Product Registration Mgr. **Date:** April 25, 2014

27

499-568

Memorandum

Date: 5 / 6 / 2014

To: 7, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- ☒ fully accepted submission
- ☐ partially accepted submission
- ☒ rejected submission

SSTC

- work w/ reg. to correct, return to Teresa Downs for rescreen under 11-3

Administrative Materials

Please read instructions on reverse before com, form.

Form Approved. OMB No. 2070-0060

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[XXX] **Registration**
[ ] **Amendment**
[ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
499-568	Reuben Baris	[ ] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
PT® Alpine® Pressurized Fly Bait	Team 7	

5. Name and Address of Applicant *(Include ZIP Code)*

BASF Corporation
26 Davis Drive
Research Triangle Park, NC 27709

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[XX] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of One-Year Storage Stability and Corrosion Characteristics Study Report per NoPR 2/18/14.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes	[ ] Yes	[ ] Yes	[XXXXX] Metal
[XX] No	[XX] No	[XX] No	[ ] Plastic
	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	[ ] Glass
			[ ] Paper
			[ ] Other (Specify) _____

Certification must be submitted

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	Range: 16 - 20 oz	[ ] Container Label

6. Manner in Which Label is Affixed to Product

[XXXX] Lithograph
[ ] Paper glued
[ ] Stenciled
[ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dana Thomas (Jenna Garwood)	Product Registration Mgr.	919-659-3930

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received
(Stamped)

2. Signature	3. Title
Dana Thomas	Product Registration Mgr.
4. Typed Name	**5. Date**
Dana M. Thomas	April 25, 2014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number [919-659-3930] BASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709	EPA Registration Number/File Symbol 499-568
Active Ingredient(s) and/or representative test compound(s) Dinotefuran, CAS #165252-70-0	Date April 25, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, Domestic Outdoor	Product Name PT® Alpine® Pressurized Fly Bait

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Dana M Thomas	4/25/14	Dana M. Thomas, Product Registration Mgr.

Form Approved OMB No. 2070-0060

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

aperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration nd special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including uggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

ate: April 25, 2014	EPA Reg. No./File Symbol: 499-568 Page 1 of 3
pplicant's/Registrant's Name & Address	Product
ASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709	PT® Alpine® Pressurized Fly Bait

gredient: Dinotefuran, CAS #165252-70-0

uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.300 - 158.355	PRODUCT CHEMISTRY				
30.1550	Product Identity	49155101	Applicant; 499	OWN	
30.1650	Manufacturing Process	49155101	Applicant; 499	OWN	
30.1670	Discussion of formation of impurities	49155101	Applicant; 499	OWN	
30.1700	Preliminary Analysis	49155101	Applicant; 499	OWN	
30.1750	Certificate of limits	49155101	Applicant; 499	OWN	
30.1800	Analytical Methods	49155101	Applicant; 499	OWN	
30.6302	Color	49155101	Applicant; 499	OWN	
30.6303	Physical State	49155101	Applicant; 499	OWN	
30.6304	Odor	49155101	Applicant; 499	OWN	
30.7200	Melting Point	49155101	Applicant; 499	OWN	
30.7220	Boiling Point	49155101	Applicant; 499	OWN	
30.7300	Density, bulk-density, or specific gravity	49155101	Applicant; 499	OWN	
30.7840 or 830.7860	Solubility	49155101	Applicant; 499	OWN	
30.7950	Vapor Pressure	49155101	Applicant; 499	OWN	

ignature Dana M Thomas

Name and Title: Dana M. Thomas
Product Registration Mgr.

Date: 4/25/14

EPA Form 8750-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

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1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

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DATA MATRIX

ate: April 25, 2014	EPA Reg. No./File Symbol: 499-568 Page 2 of 3
pplicant's/Registrant's Name & Address ASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709	Product PT® Alpine® Pressurized Fly Bait

gredient: Dinotefuran, CAS #165252-70-0

uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.300 - 158.355					
30.7370	Dissociation constant	49155101	Applicant; 499	OWN	
30.7550, 830.7560 or 830.7570	Octanol/water partition coefficient	49155101	Applicant; 499	OWN	
30.7000	pH	49155101	Applicant; 499	OWN	
30.6313	Stability	49155101	Applicant; 499	OWN	
30.6314	Oxidizing/Reducing reaction	49155101	Applicant; 499	OWN	
30.6315	Flammability	49155101	Applicant; 499	OWN	
30.6316	Explodability	49155101	Applicant; 499	OWN	
30.6317	Storage stability	TBD	Applicant; 499	OWN	Submitted 4/25/14
30.7100	Viscosity	49155101	Applicant; 499	OWN	
30.6319	Miscibility	49155101	Applicant; 499	OWN	
30.6320	Corrosion Characteristics	TBD	Applicant; 499	OWN	Submitted 4/25/14
30.6321	Dielectric breakdown voltage	49155101	Applicant; 499	OWN	

ignature
Dana M. Thomas

Name and Title: Dana M. Thomas
Product Registration Mgr.

Date:
4/25/14

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

DATA MATRIX

Date: April 25, 2014 | EPA Reg. No./File Symbol: 499-568 |

Applicant's/Registrant's Name & Address
BASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709

Product
PT® Alpine® Pressurized Fly Bait

Ingredient: Dinotefuran, CAS #165252-70-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
58.500	Toxicology				
70.1100	Acute Oral LD-50, rat	49155102	Applicant; 499	OWN	
70.1200	Acute dermal LD-50	49155103	Applicant; 499	OWN	
70.1300	Acute inhalation LC-50, rat	49155104	Applicant; 499	OWN	
70.2400	Primary eye irritation, rabbit	49155105	Applicant; 499	OWN	
70.2500	Primary dermal irritation	49155106	Applicant; 499	OWN	
70.2600	Dermal sensitization	49155107	Applicant; 499	OWN	
58.400	Product Performance				
	Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions	49155108	Applicant; 499	OWN	
	Efficacy of TC-333 Aerosol Fly Bait (1.0% Dinotefuran) against House Flies (*Musca domestica*)	49155109	Applicant; 499	OWN	
	Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica*, on Animal Confinement Facilities in Central California	49155110	Applicant; 499	OWN	
	Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*)	49155111	Applicant; 499	OWN	

Signature: Dana M Thomas

Name and Title: Dana M. Thomas
Product Registration Mgr.

Date:
4/25/14

Form Approved OMB No. 2070-0060

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Washington, DC 20460

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DATA MATRIX

Date: April 25, 2014 | EPA Reg. No./File Symbol: 499-568 | Page 1 of 3

Applicant's/Registrant's Name & Address: BASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709

Product: PT® Alpine® Pressurized Fly Bait

Ingredient: Dinotefuran, CAS #165252-70-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
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			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	

Signature: Dana M. Thomas

Name and Title: Dana M. Thomas
Product Registration Mgr.

Date: 4/25/14

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Public Use Copy

Form Approved OMB No. 2070-0060

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

DATA MATRIX

ate: April 25, 2014	EPA Reg. No./File Symbol: 499-568 Page 2 of 3
pplicant's/Registrant's Name & Address ASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709	Product PT® Alpine® Pressurized Fly Bait

gredient: Dinotefuran, CAS #165252-70-0

uideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	Submitted 4/25/14
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	Submitted 4/25/14
			Applicant; 499	OWN	

ignature
Dana M Thomas

Name and Title: Dana M. Thomas
Product Registration Mgr.

Date:
4/25/14

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

DATA MATRIX

Date: April 25, 2014	EPA Reg. No./File Symbol: 499-568 Page 3 of 3
Applicant's/Registrant's Name & Address BASF Corporation, 26 Davis Drive, Research Triangle Park NC 27709	Product PT® Alpine® Pressurized Fly Bait

Ingredient: Dinotefuran, CAS #165252-70-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	

Signature

Name and Title: Dana M. Thomas
Product Registration Mgr.

Date:
4/25/14

Kumar, Rita

From: Kumar, Rita
Sent: Thursday, December 04, 2014 4:35 PM
To: 'jennifer.herzog@basf.com'
Subject: CSF notification 499-568
Attachments: [Untitled].pdf

Dear Jennifer: Please see attached. This notification is denied, and this action is now complete.
Regards,
Rita

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 4, 2014

Jennifer Herzog
Product Registration Specialist
BASF Corporation
26 Davis Drive, PO Box 13528
Research Triangle Park, NC, 27709-3528

Subject: Notification per PRN 98-10 - Revised Alternate 1 Confidential Statement of Formulation (CSF)
Product Name: PT Alpine Pressurized Fly Bait
EPA Registration Number: 499-568
Application Date: 10/2/2014
Decision Number: 496442

Dear Ms. Herzog:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the request is not acceptable for the following reasons:

1. Please verify that BASF is now the registrant of record for this product with company number 499, and Whitmire Micro-Gen Research Laboratories, which used to have company number 499, is no longer a pesticide registrant. Also, explain why the mailing address for BASF on application form 8570-1 is not the same as address given in part 1 of revised Alternate 1 CSF.

2. The label for [redacted] does not have most of the use sites (like residential and commercial indoors) that your product is registered for, and cannot be used as an alternate source of dinotefuran for your product.

No further processing of this application will occur. You may submit a new amendment application addressing the deficiencies listed above for future consideration. Our records have been updated accordingly to note that this notification is denied. CSF Alt 1 dated 6/12/2013 remains the alternate formulation of record.

If you have any questions, you may contact Rita Kumar at 703-308-8291 or via email at kumar.rita@epa.gov.

Sincerely,

Mark Suarez, Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

BASF
The Chemical Company

October 2, 2014

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
ATTN: Mr. Reuben Baris, PM Team 7
Insecticide/Rodenticide Branch (7504P)
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Re: Minor CSF Notification – Adding Alternate Active Ingredient Supplier
PT® Alpine® Pressurized Fly Bait
EPA Reg. No. 499-568

Dear Mr. Baris:

Enclosed please find a completed application, Formulator's Exemption Statement form, and a revised Alternate CSF in support of a minor CSF notification. The enclosed Alternate 1 CSF (dated 10/2/2014) [redacted] as the new alternate Active Ingredient supplier. The Basic CSF (dated 5/6/2014) has not changed and is not included in this submission.

This revised Alternate CSF (dated 10/2/2014) will supersede the existing Alternate CSF (dated 5/6/2014). The current CSFs of record are now Basic dated 5/6/2014 and Alternate 1 dated 10/2/2014.

Thank you for your time and assistance in this matter. Please do not hesitate to contact me at (919) 547-2797 or jennifer.herzog@basf.com if you have any questions or require any additional information.

Sincerely,

Jennifer M. Herzog
Product Registration Specialist
BASF Corporation

BASF Corporation
26 Davis Drive, PO Box 13528
Research Triangle Park
NC 27709-3528
Tel: (919) 547-2000
www.basf.com/usa

e-Submission

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

EPA

United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☑ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number: 499-568

2. EPA Product Manager: Reuben Baris

3. Proposed Classification: ☐ None ☐ Restricted

4. Company/Product (Name): PT Alpine Pressurized Fly Bait

PM#: 7

5. Name and Address of Applicant *(Include ZIP Code)*

BASF Corporation
26 Davis Drive, PO Box 13528
Research Triangle Park NC 27709-3528

☐ *Check if this is a new address*

6. **Expedited Reveiw.** In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

☐ Amendment - Explain below.
☐ Resubmission in response to Agency letter dated _____
☑ Notification - Explain below.
☐ Final printed labels in repsonse to Agency letter dated _____
☐ "Me Too" Application.
☐ Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

CSF Notification [redacted] alternate Active Ingredient supplier.

Section - III

1. **Material This Product Will Be Packaged In:**

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Metal ☐ Plastic ☐ Glass ☐ Paper ☐ Other (Specify)
* ***Certification must be submitted***	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information: ☐ Label ☐ Container

4. Size(s) Retail Container

5. Location of Label Directions: ☐ on labeling adhered to container

6. Manner in Which Label is Affixed to Product: ☐ Lithograph ☐ Paper glued ☐ Stenciled ☐ Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Jennifer Herzog	Product Registration Specialist	(919) 547-2797

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

8. Date Application Received: **(Stamped)**

2. Signature: Jennifer Herzog

3. Title: Product Registration Specialist

4. Typed Name: Jennifer Herzog

5. Date: 10/2/2014

e-Submission

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

Product ingredient source information may be entitled to confidential treatment

Form Approved. OMB No. 2070-0060, 2070-0057, 2070-0107, 2070-0122, 2070-0164.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
BASF Corporation **26 Davis Dr.** **Research Triangle Park, NC 267709**	**499-568** Product Name **PT Alpine Pressurized Fly Bait** Date of Confidential Statement of Formula (EPA Form 8570-4) **(Basic dated 5/16/14 & Alternate 1 dated 10/2/14)**

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):
Dinotefuran, [N-methyl-N'-nitro-N"-(tetrahydro-3-furanyl)methyl)guanidine]
CAS # 165252-70-0

(2)

Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person, and meets the requirements of 40 CFR Section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

[X] (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

[ ] (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption

Source

Active Ingredient	Product Name	Registration Number
Dinotefuran, [N-methyl-N'-nitro-N"-(tetrahydro-3-furanyl)methyl)guanidine] CAS # 165252-70-0	[redacted]	

Signature	Name and Title	Date
	Jennifer Herzog Product Registration Specialist	10/2/2014

EPA Form 8570-27(Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Pages 44-45 - *Confidential Statements of Formula may be entitled to confidential treatment*

Material to be added to an e-Jacket/Jacket

Reg. No. 499-568 Decision # 480032

Description: New product registration

1. Placement within the e-Jacket/jacket:
   - ☐ Default: (chronological, top = newest)
   - ☐ File Location: (eg. "before page 45 in .pdf")

2. ☐ Send to Data Extraction contractors this material:
   - ☑ Newly stamped accepted label
   - ☐ Notification
   - ☑ New CSF
   - ☐ Other: _____

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Rita Kumar Division: RD

Phone: 308-8291 Date: 2-18-14

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:	Date of Issuance:
499-568	FEB 1 8 2014

Term of Issuance: Conditional

NOTICE OF PESTICIDE:
_x_ Registration
__ Reregistration
(under FIFRA, as amended)

Name of Pesticide Product:
PT Alpine Pressurized Fly Bait

Name and Address of Registrant (include ZIP Code):

Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Industrial Boulevard
St. Louis, MO 63122-6682

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data. You must comply with DCI ID# GDCI 044312-1147 issued on 3/1/2013. If you have questions about the Generic DCI issued, you may contact Steven Snyderman from the Pesticide Re-evaluation Division.

2. Submit the following data: One year storage stability (830.6317) and corrosion characteristics (830.6320) studies. These studies can be run concurrently. Observation must be made at 0, 3, 6, 9, and 12 months period and the results must be submitted to the Agency upon completion. These studies must be submitted within 15 months from the date of this letter.

3. Make the following label change:

Add the phrase "EPA Registration Number 499-568" to the front panel.

Signature of Approving Official:	Date:
for Meredith Laws, Chief Insecticide Rodenticide Branch	02/18/14

EPA Form 8570-6

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Submit two copies of the revised final printed label before you release the product for shipment. Your release for shipment of the product constitutes acceptance of these conditions.

Please be reminded that 40 CFR Part 156.140(a)(4) requires that a batch code, lot number, or other code identifying the batch of the pesticide distributed and sold be placed on non-refillable containers. The code may appear either on the label or durably marked on the container itself, and can be added by non-notification per PRN 98-10.

A stamped copy of the label is enclosed for your records. If you have any questions, contact Rita Kumar at (703) 308-8291, or kumar.rita@epa.gov.

Sincerely,

Meredith Laws, Chief
Insecticide Rodenticide Branch
Registration Division (7505P)

Enclosure

PT® ALPINE®

Pressurized Fly Bait

KILLS: House Flies, Filth Flies, Lesser House Flies, Flesh Flies and Small Fruit or Vinegar Flies

FOR USE IN AND AROUND: Commercial, Residential, Industrial Buildings and Other Manmade Structures, Garbage or Refuse Bins and Receptacles, or other areas flies may be a nuisance or health hazard. [Apartments; Bakeries; Campgrounds; Carnivals; Circus; Concert Arenas; Condominiums; Confectionaries; County and State Fair Facilities; Dairy Areas; Farm Houses; Day Care Facilities; Festival Grounds, Food Handling Establishments; Food Processing Plants; Food Storage Areas; Food Vending Structures; Garages; Golf Courses; Grain Mills; Granaries; Homes; Hospitals; Hotels; Housing and Containment Areas (i.e., Arenas, Barns, Cages, Hatcheries, Houses, Hutches, Kennels, Parlors, Pens, Sheds, Shelters, Stables) for Animals (i.e., Avian, Bovine, Canine, Equine, Feline, Hircine, Leporine, Murine, Porcine); Interiorscapes; LEED Buildings (as specified below); Libraries; Marinas; Meat, Poultry & Egg Processing Facilities; Meat Packing Plants; Milk Rooms; Mobile Homes; Motor Homes; Motels; Museums; Nursing Homes; Outdoor Living Areas; Pavilions; Porches; Research Facilities; Resorts; Restaurants; Mobile Food Vendors; Parking Ramps; Poultry Facilities (including: Hatchery, Egg Packaging, Breeding Facilities); Public Picnic Areas; Public Restrooms; Recreational Rest Areas; Residential Backyards; Schools; Supermarkets; Tents or Temporary Shelters; Theme Parks; Terminals; Transportation Equipment (Buses, Barges, Boats, Ships, Trailers, Trains, Trucks); Utilities; Warehouses; Waysides; Wildlife Refuge Areas; Zoos]

ACCEPTED
FEB 1 8 2014
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under:
EPA. Reg. No: 499-568

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No 499-LAI EPA Est. No. 7969-MO-1

Net Weight: _____

ACTIVE INGREDIENT:

Dinotefuran, N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine	1.0%
OTHER INGREDIENTS:	99.0%
Total:	100.0%

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may also call 1-800-832-HELP (4357), 24 hrs/day, 7/days/week.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in water adjacent to treated areas.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are foraging in the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

SMART SOLUTIONS FACTS	
A ready-to-use solution to kill flies in a broad range of urban environments. Provides attractancy properties which will aid in bringing flies into the treated bait area. Key attributes of this product include:	
PT® Alpine® Pressurized Fly Bait	▪ Quick Knockdown ▪ Proven attractancy for up to 30 days ▪ Kills flies for up to 30 days on non-porous surfaces. ▪ May be used in conjunction with a fly light program such as Vector Plasma®, Vector Plasma One® and Vector® Classic® for monitoring of results and fly population reduction. ▪ For best management practices, use the bait as part of an overall Integrated Pest Management (IPM) program utilizing residuals and contact sprays, traps and drain cleaners. For questions or comments, call 1-800-777-8570.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Read Entire Label. Use strictly in accordance with Precautionary Statements and Directions for Use, and with applicable state and federal regulations. Apply bait only in areas that are out of reach of children and pets.

USE RESTRICTIONS

- Do not apply bait to surfaces which may reach excessive temperatures. Examples include portions of stoves, lighting above food preparation areas, ovens, grills, fume hoods, steam tables, toasters, fryers, dishwashers and hot water pipes.
- Do not apply directly on food preparation surfaces or dining surfaces where foods for consumption may come in contact.
- Do not apply bait in areas where animals can ingest product.
- Do not apply directly upon animals.
- Do not apply to milking equipment in dairy areas.
- Do not apply directly into any electronic equipment or areas where electrical short circuit could occur.
- Do not use in aircraft cabins; use in cargo areas only.

APPLICATION INSTRUCTIONS

AREA TREATMENT: Point can toward target area from a distance no further than 12 in (30 cm) and press down actuator. Make a light application at a rate of 2 ln ft/sec and avoid run off or dripping from targeted area. Area treatments are effective where flies congregate, roost and feed, which may include garbage receptacles and lids, refuge containers, under tables and benches, recycling bins, dumpsters, behind vending machines, plant/flower pots, under bars, calf hutch ceilings, eave areas, walls and/or areas where flies are likely to congregate or infest. Do not apply bait in areas that are frequently cleaned. This product will not adhere to surfaces that are dusty or greasy. Reapply when bait placements are no longer visible and/or reinfestation occurs. Use a water-dampened paper towel to remove unwanted bait placements and then discard in trash.

BAND TREATMENT: Spray from a distance no further away from targeted area than 6 in (15 cm) to create a band application at a rate of 2 In ft/sec. Band applications may be made to areas such as beam edges, receptacle edges, table or bench edges, around windows and window frames, under narrow eaves and other areas where there is a narrow area where flies land, roost and/or are likely to infest. Reapply when bait placements are no longer visible and/or reinfestation occurs. Use water-dampened paper towel to remove unwanted bait placements and then discard in trash.

REMOVABLE BAIT PLACEMENTS: Spray bait on a small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine of at least 6 in long. Object may be made of wood, plastic, cardboard, index cards, nylon, metal or other suitable material. Place in areas of fly activity, and out of reach of children and domestic animals.

FOOD HANDLING ESTABLISHMENTS: Food/Feed handling establishments are places other than private residences in which food is held, processed, prepared or served, including those operating under the Federal meat, poultry, shell egg grading and egg products inspection programs.

Use within food preparation and food production areas of food handling establishments is limited to the interior of refuge receptacles, removable bait placements or in stations. For areas outside of the food preparation and food production rooms, spot and/or band applications may be made to areas where flies congregate and rest.

Food/Feed Areas: Include areas for receiving, serving, storing (dry, cold, frozen, raw), packing (canning, bottling, wrapping, boxing), preparing (cleaning, slicing, cooking, grinding), edible waste storage and enclosed processing systems (mills, dairies, edible oils, syrups).

All removable bait placements must be clearly marked with the wording "Fly Bait, Do not touch" (written, typed or stickered on it) and must be secured to the surface with an adhesive material or tape. Placements should be recorded and inspected with each service to that area. **Do not place removable bait placements over or on food preparation or food processing areas. The use of rope or twine is not allowed in food areas.**

Non-Food/Feed Areas: Include areas such as garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage areas (after packaging, canning or bottling).

All removable bait placements must be clearly marked with the wording "Fly Bait, Do not touch". Place in areas conducive to fly activity, and out of reach of children and pets.

Rope & Twine: Hang in areas where flies roost and/or congregate. Place a sticker or label clearly marked with the wording "Fly Bait, Do not touch" (written or typed) at the bottom of the rope or twine. Place in areas out of reach of children, pets and livestock.

PREVENTATIVE FLY PROGRAMS: This product may be used as part of a preventative program or in anticipation of a fly problem associated with an event. Event examples include weddings, picnics, birthday parties, family reunions, graduation parties, etc. Apply inside all garbage receptacles, underneath garbage lids, inside recycling bins or receptacles, and other labeled areas that will help prevent flies from being a nuisance.

LEED (Leadership in Energy and Environmental Design) Buildings or GreenPro Programs: Apply inside of sealable containers including mouse stations, fly bait stations or handmade containers with access for the flies. Flies must be active within the building for this application. Do not use as a preventative control product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry area away from heat or open flame and inaccessible to children.

PESTICIDE DISPOSAL: Wastes resulting from use of this product may be disposed of on site, in accordance with the label directions, or at an approved waste disposal facility.

CONTAINER HANDLING & DISPOSAL: Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

Contains no CFCs or other ozone depleting substances.
Federal regulations prohibit CFC propellants in aerosols.

CONDITIONS OF SALE AND WARRANTY

Follow the **Directions for Use**. It is impossible to eliminate all risks inherently associated with use of this product, and therefore all such risk shall be assumed by the Buyer. Whitmire warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use**, subject to the inherent risks, referred to above. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW: (A) WHITMIRE MAKES NO OTHER WARRANTIES EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY, (B) BUYER'S EXCLUSIVE REMEDY AND WHITMIRE'S AND SELLER'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THE PRODUCT, AND (C) WHITMIRE AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. Whitmire and the Seller offer this product, and the Buyer accepts it, subject to these **Conditions of Sale and Warranty** which may be varied only by agreement in writing signed by a duly authorized representative of Whitmire.

Manufactured for:
Whitmire Micro-Gen Research Laboratories, Inc.®
by BASF Corporation
3568 Tree Court Industrial Blvd.
St. Louis MO 63122-6682
Questions? Call 1-800-777-8570

Kumar, Rita

From: Kumar, Rita
Sent: Wednesday, February 19, 2014 11:07 AM
To: 'Dana M Thomas'
Cc: Baris, Reuben
Subject: RE: FW: 499-568 reg notice and label.

Dana: This is a conditional registration because dinotefuran is undergoing registration review, and a GDCI was sent last year which is still open. This is the standard language we are using for all chemicals that are undergoing registration review and have an open GDCI. If you are a not a generic registrant, then you would not get the GDCI.

I hope this answers your question.
Rita

From: Dana M Thomas [mailto:dana.thomas@basf.com]
Sent: Wednesday, February 19, 2014 10:14 AM
To: Kumar, Rita
Cc: Baris, Reuben
Subject: Re: FW: 499-568 reg notice and label.

Rita, thank you for sending via email. I have a couple of questions:

1. Why is this a conditional registration? Is it because of the one year storage stability and corrosion characteristics study(ies)?

2. When stating we must comply with DCI ID #GDCI 044312-1147 issued on 3/1/2013, does this mean now or when the Agency requires all registrants of similar products to submit such data? I'm asking because we did not receive the GDCI for dinotefuran.

Please advise. Thank you.

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Dana M Thomas <dana.thomas@basf.com>
Cc: "Baris, Reuben" <Baris.Reuben@epa.gov>
Date: 02/18/2014 01:51 PM
Subject: FW: 499-568 reg notice and label.

Please see attached. Thia action is now complete. Please acknowledge receipt.
Thanks,
Rita

Kumar, Rita

Resubmission: S 947811

From: Dana M Thomas [dana.thomas@basf.com]
Sent: Tuesday, February 11, 2014 6:15 PM
To: Kumar, Rita
Cc: Baris, Reuben
Subject: Re: FW: FW: 499-LAI efficacy review
Attachments: 000499-00LAI.20140211v101.PT Alpine Pressurized Fly Bait.pdf

Rita, attached is the revised label, as requested (includes revisions requested in your previous email).

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Dana M Thomas <dana.thomas@basf.com>
Cc: "Baris, Reuben" <Baris.Reuben@epa.gov>
Date: 02/11/2014 01:55 PM
Subject: FW: FW: 499-LAI efficacy review

Also put the two last sentences in Food/Feed Areas paragraph on page 3 in bold text or under a subheading Restrictions.
Rita

From: Kumar, Rita
Sent: Tuesday, February 11, 2014 10:17 AM
To: 'Dana M Thomas'
Subject: FW: FW: 499-LAI efficacy review

Dana: there is one more change needed to this label. Since this is a pressurized spray, on page 2, last paragraph titled Removable Bait Placements, replace the word "Apply" with "Spray" in the first sentence.
Please submit revised label today, if possible.
Thanks,
Rita

From: Kumar, Rita
Sent: Monday, February 10, 2014 5:39 PM
To: Dana M Thomas
Cc: Baris, Reuben
Subject: RE: FW: 499-LAI efficacy review

Hi Dana: Please see response from our efficacy folks below:

For consistency purposes, they can have flesh flies and filth flies and I won't look at the data now but may sometime in the future.
As for the bait stations, if the station is only meant as a protector of bait or to keep non-targets out of it then it is probably OK assuming that its openings are large enough to allow appropriate fly access. If the bait stations acts more like a trap, then it may require testing due to visual attractant cues.

Hope this helps you in finalizing the label. I would like to have the revised label tomorrow, so that we can finish this action this week.
Thanks,
Rita

From: Dana M Thomas <dana.thomas@basf.com>
Sent: Wednesday, January 29, 2014 5:16 PM
To: Kumar, Rita
Cc: Baris, Reuben; Urbanski, Jennifer
Subject: Re: FW: 499-LAI efficacy review

Dear Rita & Jennifer,

I forwarded the efficacy review to our biology folks, and we have the following comments to the recommended label revisions:

1. We have data for flesh flies, blue bottle flies, phorid flies, and red fruit flies. However, we did not submit these reports for review because we didn't believe these flies to be public health pests as defined by PRN 2002-1 and, therefore, not required to be submitted. In each of these studies, PT Alpine Pressurized Fly Bait outperformed the commercial standard (QuickBayt). If you would like to see any or all of these data reports, I would be happy to send them via email. Please reconsider the recommendation to delete references to filth flies and flesh flies. At the very least, would it be acceptable to claim "aids in the control of filth flies and flesh flies"?
1.
PRN 2002-1 lists the following flies as public health pests:
Flies, mosquitoes, midges, gnats: Diptera
Black Flies, black gnats: Simuliidae (many species)
House Fly: Musca domestica
Stable Fly: Stomoxys calcitrans
Little House Fly: Fannia canicularis
Horse Flies, Deer Flies and Greenheads: Tabanidae (many species)

2. With regard to use of the product in bait stations, this product is all about odor cues. PT Alpine Pressurized Fly Bait is clear, so there are no color cues to attract the flies. Biologically, flies are known to enter small spaces/areas, if they are attracted to the odor therein. Obviously flies are attracted to this bait, so it stands to reason that flies will enter a bait station containing this material. An analogy is that of a rodent station where flies are attracted by decaying material within the station, and have been seen by the hundreds. This product is also somewhat sticky/tacky to the touch, so we included the option of using the product in a bait station (loosely defined as: installed fly light traps, mouse stations, fly bait stations or handmade containers with access for flies) for more sensitive areas and accounts (i.e. food areas and LEED buildings or GreenPro programs).

Thank you for your consideration of this information. I look forward to your response.

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.
Authorized Agent for Whitmire Micro-Gen Research Laboratories, Inc.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA
BASF - The Chemical Company
Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Dana M Thomas <dana.thomas@basf.com>
Cc: "Baris, Reuben" <Baris.Reuben@epa.gov>
Date: 01/28/2014 03:21 PM
Subject: FW: 499-LAI efficacy review

Dear Dana: Please see attached efficacy review for this new product, and make label changes as specified on page 3. The acute toxicity data are still in review, further label changes may be required when that review is complete.
Regards,
Rita

Kumar, Rita

From: Kumar, Rita
Sent: Tuesday, February 11, 2014 2:55 PM
To: 'Dana M Thomas'
Cc: Baris, Reuben
Subject: FW: FW: 499-LAI efficacy review

Importance: High

Also put the two last sentences in Food/Feed Areas paragraph on page 3 in bold text or under a subheading Restrictions.
Rita

From: Kumar, Rita
Sent: Tuesday, February 11, 2014 10:17 AM
To: 'Dana M Thomas'
Subject: FW: FW: 499-LAI efficacy review

Dana: there is one more change needed to this label. Since this is a pressurized spray, on page 2, last paragraph titled Removable Bait Placements, replace the word "Apply" with "Spray" in the first sentence.
Please submit revised label today, if possible.
Thanks,
Rita

From: Kumar, Rita
Sent: Monday, February 10, 2014 5:39 PM
To: Dana M Thomas
Cc: Baris, Reuben
Subject: RE: FW: 499-LAI efficacy review

Hi Dana: Please see response from our efficacy folks below:

For consistency purposes, they can have flesh flies and filth flies and I won't look at the data now but may sometime in the future.
As for the bait stations, if the station is only meant as a protector of bait or to keep non-targets out of it then it is probably OK assuming that its openings are large enough to allow appropriate fly access. If the bait stations acts more like a trap, then it may require testing due to visual attractant cues.

Hope this helps you in finalizing the label. I would like to have the revised label tomorrow, so that we can finish this action this week.
Thanks,
Rita

From: Dana M Thomas <dana.thomas@basf.com>
Sent: Wednesday, January 29, 2014 5:16 PM
To: Kumar, Rita
Cc: Baris, Reuben; Urbanski, Jennifer
Subject: Re: FW: 499-LAI efficacy review

Dear Rita & Jennifer,

I forwarded the efficacy review to our biology folks, and we have the following comments to the recommended label revisions:

1. We have data for flesh flies, blue bottle flies, phorid flies, and red fruit flies. However, we did not submit these reports for review because we didn't believe these flies to be public health pests as defined by PRN 2002-1 and, therefore, not required to be submitted. In each of these studies, PT Alpine Pressurized Fly Bait outperformed the commercial standard (QuickBayt). If you would like to see any or all of these data reports, I would be happy to send them via email. Please reconsider the recommendation to delete references to filth flies and flesh flies. At the very least, would it be acceptable to claim "aids in the control of filth flies and flesh flies"?

1.

PRN 2002-1 lists the following flies as public health pests:
Flies, mosquitoes, midges, gnats: Diptera
Black Flies, black gnats: Simuliidae (many species)
House Fly: Musca domestica
Stable Fly: Stomoxys calcitrans
Little House Fly: Fannia canicularis
Horse Flies, Deer Flies and Greenheads: Tabanidae (many species)

2. With regard to use of the product in bait stations, this product is all about odor cues. PT Alpine Pressurized Fly Bait is clear, so there are no color cues to attract the flies. Biologically, flies are known to enter small spaces/areas, if they are attracted to the odor therein. Obviously flies are attracted to this bait, so it stands to reason that flies will enter a bait station containing this material. An analogy is that of a rodent station where flies are attracted by decaying material within the station, and have been seen by the hundreds. This product is also somewhat sticky/tacky to the touch, so we included the option of using the product in a bait station (loosely defined as: installed fly light traps, mouse stations, fly bait stations or handmade containers with access for flies) for more sensitive areas and accounts (i.e. food areas and LEED buildings or GreenPro programs).

Thank you for your consideration of this information. I look forward to your response.

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.
Authorized Agent for Whitmire Micro-Gen Research Laboratories, Inc.
Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA
BASF - The Chemical Company
Pest Control Solutions

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Rita

Kumar, Rita

Resubmission: S947592

From: Dana M Thomas [dana.thomas@basf.com]
Sent: Tuesday, February 11, 2014 11:43 AM
To: Kumar, Rita
Cc: Baris, Reuben
Subject: Re: FW: FW: 499-LAI efficacy review
Attachments: 000499-00LAI.20140211v101.PT Alpine Pressurized Fly Bait.pdf

Good morning, Rita.

Attached is a revised draft label. I replaced "Apply" with "Spray" under "Removable Bait Placements" as you requested. Based on the response from the efficacy folks, I kept flesh and filth flies on the label, and removed any reference to applying the product to insect light trap sticky boards or in insect light traps. The product may still be used in conjunction with a fly light program, and in bait stations to protect the bait and/or the surrounding environment. Please let me know if you have any questions.

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Dana M Thomas <dana.thomas@basf.com>
Date: 02/11/2014 09:17 AM
Subject: FW: FW: 499-LAI efficacy review

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Subject: Re: FW: 499-LAI efficacy review

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Thank you for your consideration of this information. I look forward to your response.

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.
Authorized Agent for Whitmire Micro-Gen Research Laboratories, Inc.
Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

PT® ALPINE®

Pressurized Fly Bait

KILLS: House Flies, Filth Flies, Lesser House Flies, Flesh Flies and Small Fruit or Vinegar Flies

FOR USE IN AND AROUND: Commercial, Residential, Industrial Buildings and Other Manmade Structures, Garbage or Refuse Bins and Receptacles, or other areas flies may be a nuisance or health hazard. [Apartments; Bakeries; Campgrounds; Carnivals; Circus; Concert Arenas; Condominiums; Confectionaries; County and State Fair Facilities; Dairy Areas; Farm Houses; Day Care Facilities; Festival Grounds, Food Handling Establishments; Food Processing Plants; Food Storage Areas; Food Vending Structures; Garages; Golf Courses; Grain Mills; Granaries; Homes; Hospitals; Hotels; Housing and Containment Areas (i.e., Arenas, Barns, Cages, Hatcheries, Houses, Hutches, Kennels, Parlors, Pens, Sheds, Shelters, Stables) for Animals (i.e., Avian, Bovine, Canine, Equine, Feline, Hircine, Leporine, Murine, Porcine); Interiorscapes; LEED Buildings (as specified below); Libraries; Marinas; Meat, Poultry & Egg Processing Facilities; Meat Packing Plants; Milk Rooms; Mobile Homes; Motor Homes; Motels; Museums; Nursing Homes; Outdoor Living Areas; Pavilions; Porches; Research Facilities; Resorts; Restaurants; Mobile Food Vendors; Parking Ramps; Poultry Facilities (including: Hatchery, Egg Packaging, Breeding Facilities); Public Picnic Areas; Public Restrooms; Recreational Rest Areas; Residential Backyards; Schools; Supermarkets; Tents or Temporary Shelters; Theme Parks; Terminals; Transportation Equipment (Buses, Barges, Boats, Ships, Trailers, Trains, Trucks); Utilities; Warehouses; Waysides; Wildlife Refuge Areas; Zoos]

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No 499-LAI EPA Est. No. 7969-MO-1

Net Weight: _____

ACTIVE INGREDIENT:

Dinotefuran, N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine	1.0%
OTHER INGREDIENTS:	99.0%
Total:	100.0%

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may also call 1-800-832-HELP (4357), 24 hrs/day, 7/days/week.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in water adjacent to treated areas.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

SMART SOLUTIONS FACTS	
A ready-to-use solution to kill flies in a broad range of urban environments. Provides attractancy properties which will aid in bringing flies into the treated bait area. Key attributes of this product include:	
PT® Alpine® Pressurized Fly Bait	▪ Quick Knockdown ▪ Proven attractancy for up to 30 days ▪ Kills flies for up to 30 days on non-porous surfaces. ▪ May be used in conjunction with a fly light program such as Vector Plasma®, Vector Plasma One® and Vector® Classic® for monitoring of results and fly population reduction. ▪ For best management practices, use the bait as part of an overall Integrated Pest Management (IPM) program utilizing residuals and contact sprays, traps and drain cleaners. For questions or comments, call 1-800-777-8570.

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Read Entire Label. Use strictly in accordance with Precautionary Statements and Directions for Use, and with applicable state and federal regulations. Apply bait only in areas that are out of reach of children and pets.

USE RESTRICTIONS

- Do not apply bait to surfaces which may reach excessive temperatures. Examples include portions of stoves, lighting above food preparation areas, ovens, grills, fume hoods, steam tables, toasters, fryers, dishwashers and hot water pipes.
- Do not apply directly on food preparation surfaces or dining surfaces where foods for consumption may come in contact.
- Do not apply bait in areas where animals can ingest product.
- Do not apply directly upon animals.
- Do not apply to milking equipment in dairy areas.
- Do not apply directly into any electronic equipment or areas where electrical short circuit could occur.
- Do not use in aircraft cabins; use in cargo areas only.

APPLICATION INSTRUCTIONS

AREA TREATMENT: Point can toward target area from a distance no further than 12 in (30 cm) and press down actuator. Make a light application at a rate of 2 In ft/sec and avoid run off or dripping from targeted area. Area treatments are effective where flies congregate, roost and feed, which may include garbage receptacles and lids, refuge containers, under tables and benches, recycling bins, dumpsters, behind vending machines, plant/flower pots, under bars, calf hutch ceilings, eave areas, walls and/or areas where flies are likely to congregate or infest. Do not apply bait in areas that are frequently cleaned. This product will not adhere to surfaces that are dusty or greasy. Reapply when bait placements are no longer visible and/or reinfestation occurs. Use a water-dampened paper towel to remove unwanted bait placements and then discard in trash.

BAND TREATMENT: Spray from a distance no further away from targeted area than 6 in (15 cm) to create a band application at a rate of 2 In ft/sec. Band applications may be made to areas such as beam edges, receptacle edges, table or bench edges, around windows and window frames, under narrow eaves and

other areas where there is a narrow area where flies land, roost and/or are likely to infest. Reapply when bait placements are no longer visible and/or reinfestation occurs. Use water-dampened paper towel to remove unwanted bait placements and then discard in trash.

REMOVABLE BAIT PLACEMENTS: Spray bait on a small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine of at least 6 in long. Object may be made of wood, plastic, cardboard, index cards, nylon, metal or other suitable material. Place in areas of fly activity.

FOOD HANDLING ESTABLISHMENTS: Food/Feed handling establishments are places other than private residences in which food is held, processed, prepared or served, including those operating under the Federal meat, poultry, shell egg grading and egg products inspection programs.

Use within food preparation and food production areas of food handling establishments is limited to the interior of refuge receptacles, removable bait placements or in stations. For areas outside of the food preparation and food production rooms, spot and/or band applications may be made to areas where flies congregate and rest.

Food/Feed Areas: Include areas for receiving, serving, storing (dry, cold, frozen, raw), packing (canning, bottling, wrapping, boxing), preparing (cleaning, slicing, cooking, grinding), edible waste storage and enclosed processing systems (mills, dairies, edible oils, syrups).

All removable bait placements must be clearly marked with the wording "Fly Bait, Do not touch" (written, typed or stickered on it) and must be secured to the surface with an adhesive material or tape. Placements should be recorded and inspected with each service to that area. Do not place removable bait placements over or on food preparation or food processing areas. The use of rope or twine is not allowed in food areas.

Non-Food/Feed Areas: Include areas such as garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage areas (after packaging, canning or bottling).

All removable bait placements must be clearly marked with the wording "Fly Bait, Do not touch". Place in areas conducive to fly activity, and out of reach of children and pets.

Rope & Twine: Hang in areas where flies roost and/or congregate. Place a sticker or label clearly marked with the wording "Fly Bait, Do not touch" (written or typed) at the bottom of the rope or twine. Place in areas out of reach of children, pets and livestock.

PREVENTATIVE FLY PROGRAMS: This product may be used as part of a preventative program or in anticipation of a fly problem associated with an event. Event examples include weddings, picnics, birthday parties, family reunions, graduation parties, etc. Apply inside all garbage receptacles, underneath garbage lids, inside recycling bins or receptacles, and other labeled areas that will help prevent flies from being a nuisance.

LEED (Leadership in Energy and Environmental Design) Buildings or GreenPro Programs: Apply inside of sealable containers including mouse stations, fly bait stations or handmade containers with access for the flies. Flies must be active within the building for this application. Do not use as a preventative control product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry area away from heat or open flame and inaccessible to children.

PESTICIDE DISPOSAL: Wastes resulting from use of this product may be disposed of on site, in accordance with the label directions, or at an approved waste disposal facility.

CONTAINER HANDLING & DISPOSAL: Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

Contains no CFCs or other ozone depleting substances.
Federal regulations prohibit CFC propellants in aerosols.

CONDITIONS OF SALE AND WARRANTY

Follow the **Directions for Use**. It is impossible to eliminate all risks inherently associated with use of this product, and therefore all such risk shall be assumed by the Buyer. Whitmire warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use**, subject to the inherent risks, referred to above. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW: (A) WHITMIRE MAKES NO OTHER WARRANTIES EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY, (B) BUYER'S EXCLUSIVE REMEDY AND WHITMIRE'S AND SELLER'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THE PRODUCT, AND (C) WHITMIRE AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. Whitmire and the Seller offer this product, and the Buyer accepts it, subject to these **Conditions of Sale and Warranty** which may be varied only by agreement in writing signed by a duly authorized representative of Whitmire.

Manufactured for:
Whitmire Micro-Gen Research Laboratories, Inc.®
by BASF Corporation
3568 Tree Court Industrial Blvd.
St. Louis MO 63122-6682
Questions? Call 1-800-777-8570

Kumar, Rita

From: Urbanski, Jennifer
Sent: Wednesday, February 05, 2014 12:36 PM
To: Kumar, Rita
Subject: RE: FW: efficacy for 499-LAI

Hi Rita, for consistency purposes, they can have flesh flies and filth flies and I won't look at the data now but may sometime in the future.
As for the bait stations, if the station is only meant as a protector of bait or to keep non-targets out of it then it is probably OK assuming that its openings are large enough to allow appropriate fly access. If the bait stations acts more like a trap, then it may require testing due to visual attractant cues.

From: Kumar, Rita
Sent: Wednesday, February 05, 2014 8:54 AM
To: Urbanski, Jennifer
Subject: FW: FW: efficacy for 499-LAI

Hi Jenn: Have you been able to discuss this with Kevin? The PRIA date is coming up, so I need to wrap this up.
Thanks,
Rita

Kumar, Rita

Resubmission:
S946928

From: Dana M Thomas [dana.thomas@basf.com]
Sent: Wednesday, January 29, 2014 5:17 PM
To: Kumar, Rita
Cc: Baris, Reuben; Urbanski, Jennifer
Subject: Re: FW: 499-LAI efficacy review
Attachments: [Untitled].pdf

Dear Rita & Jennifer,

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BASF - The Chemical Company

Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP Bar Code: 413108; EPA Reg/File No.: 499-LAI APPLICANT: Whitmire Micro Gen
DECISION: 480032 PC Code(s): 044312-Dinotefuran (1.0%) PRIA:310

DATE: January 16, 2014

SUBJECT: Product Chemistry Review PT Alpine Pressurized Fly Bait

FROM: Akiva Abramovitch, Ph.D.
Technical Review Branch / RD (7505P)

THROUGH: Shyam Mathur, Ph.D.
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

01/17/14

TO: Rita Kumar/Reuben Baris, PM 7
Insecticide-Rodenticide Branch/ RD (7505C)

Formulation Type: Liquid Spray On-RTU

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product containing Dinotefuran at 1.0%. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 491551-01). The CSFs of the basic and alternate formulations 1 were all dated June 12, 2013 and were submitted along with the product label..

TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSFs dated 6/12/ 2013.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Dinotefuran (1.0%)

2. Has the registrant claimed substantial similarity to a registered product?

   [ ] Yes; [X] No; [ ] NA; if yes give the registration number of the cited product.

3. All the source materials for the active ingredients are derived from the registered sources:
   [X] Yes; [ ] No.

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: [X] Yes; [ ] No.

5. Confidential Statement of Formula(s):

   [X] Basic and Alternate CSF 1 dated June 12, 2013;

6. Product label

   a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

      [X] Yes, if not, explain below:

      Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?
      [X] Yes; [ ] No; if not, explain below:

      Metallic equivalent: [ ] Yes [X] NA;
      Soluble arsenic: [ ] Yes [X] NA
      Isomeric ratios: [ ] Yes [X] NA
      Acid equivalent: [ ] Yes [X] NA; {name} acid equivalent = xx %

   b. Health related sub statements: Product contains?

      Petroleum distillate at > 10%: [ ] Yes [X] No [ ] NA
      Methanol at > 4%: [ ] Yes [X] No [ ] NA
      Sodium nitrate/Sodium nitrite [ ] Yes [X] No [ ] NA

   c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
      [X Yes [] No
      Flammable

      Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
      [X] Yes, [ ] No, [ ] NA, if not explain below:

   d. Label requires an additional Storage and Disposal statement:
   [X] Yes [] No

7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	491551-01
830.1600	Description of materials used to produce the product		X		A	491551-01
830.1650	Description of formulation process		X		A	491551-01
830.1670	Discussion on the formation of impurities		X		A	491551-01
830.1700	Preliminary analysis			X	NA	
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	491551-01
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A (HPLC method)	491551-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress, NA = Not Applicable; U = Upgradeable

8. Group B:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Pale yellow liquid	A	491551-01
830.6315	Flammability	Flame projection 7"-No Flash back	A	491551-01
830.6316	Explodability	NA, not considered to be potentially explosive	A	491551-01
830.7000	pH	8.94 at 24.4 C	A	491551-01
830.7300	Density (units)	1.000 gm/ml at 20 C	A	491551-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request,
NA = Not applicable, I = In progress, U = Upgradeable

DP Bar Code: 413108; EPA Reg/File No.: 499-LAI APPLICANT: Whitmire Micro Gen
DECISION: 480032 PC Code(s): 044312-Dinotefuran (1.0%) PRIA:310

CONCLUSIONS:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic and alternate formulations #1 all dated June 12, 2013 are acceptable. All the ingredients in the formulations have been approved for the uses cited on the label.

2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product) , 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.

3. The product chemistry data/waiver requests corresponding to guidelines 830.6302 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation/reduction), 830.6315 (flammability), 830.6316 (explodability), 830.7000 (pH), 830.7100 (viscosity), and 830.7300 (density) are acceptable.

4. The storage stability (guideline 830.6317) and corrosion characteristics (guideline 830.6320) studies were not submitted. These physical/chemical properties are required and it is recommended that observations should be made at 0, 3, 6, 9, and 12 month intervals.

5. The proposed label was screened as it pertains to the product chemistry requirements. The review of the proposed label and uses are the purview of the RM team.

Pages 73-75 - *Confidential Statements of Formula may be entitled to confidential treatment*

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Rita Kumar

From: Jennifer Urbanski, Ph.D. 1/23/14

Date: 1/23/14

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD

DP barcode: 413112
Decision no.: 480032
Submission no: 936866
Action code: R310
Product Name: PT Alpine Pressurized Fly Bait
EPA Reg. No or File Symbol: 499-LAI
Formulation Type: fly bait spray
Ingredients statement from the label: 044312, dinotefuran (1%)
Application rate(s) of product and each active ingredient: 2 linear feet of spraying/second

I. Action Requested: Determine if the data submitted support the registration of the product to control house flies, lesser house flies, filth flies, and flesh flies.

II. MRID Summary (DERs attached):

49155108
(1) GLP or non-GLP? Non-GLP
(2) State the purpose and briefly summarize the methods and results: A study was conducted to evaluate the efficacy of two experimental fly bait aerosol formulations (dinotefuran), an industry standard (QuickBayt® [imidacloprid]), and an untreated control against caged adult house flies, *Musca domestica* (SRL Hilmar Strain). Fly baits were evaluated in 18"x 18"x 18" screen cages in the laboratory with an average of 103.1 adult house flies per each of 3 replicates per treatment. Water and an alternate food source were also provided. The experimental baits were poured on and spread out to cover one side of a 6"x 6" x1/8" fiberglass reinforced panel. The average amount of bait applied was 2.76-3.3 g for the dinotefuran products, and 1.26 for QuickBayt. Panels were allowed to dry horizontally in the laboratory for 2 hours, aided with a fan, but remained tacky to the touch throughout the test. Bait panels were attached to the rear wall of the test cages with wire. All flies were mechanically aspirated from the rearing cages, anesthetized with CO_2 in the aspirator, and then placed into the test cages. The flies were allowed to recover for 1 hour before bait panel placement and the start of the test. Controls were treated in a same manner as all treatments. House flies were assessed for knockdown at 1 and 3 hours on day 0 and once daily for three (3) days post-treatment. Mortality was determined when the fly was not moving and all dead flies were removed from the test cage.

At 1 and 3 hours post treatment, ~one-third of the flies were knocked down for the three treatments. At the end of day 3, the total mortality was 93.5% for the one dinotefuran formulation (237-093 2HPTone), 81.4% for the other dinotefuran formulation (237-094 Lq-BUT), and 82.4% for QuickBayt. Control mortality was acceptable throughout the study.
3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials: Only 237-094 Lq-BUT showed acceptable mortality 3 days after exposure. Note that the method of

application in the study (pouring on bait) differs from the label (spraying on bait). The two formulations used, while similar to the proposed product, are not equivalent.
(4) Is the study acceptable or not? Supplemental

49155109
(1) GLP or non-GLP? Non-GLP
(2) State the purpose and briefly summarize the methods and results: A study was conducted to determine the efficacy of two formulations of TC-333 Aerosol Fly Bait and QuickBayt (EPA Reg # 11556-147) against house flies (*Musca domestica*). The 5" x 7" aluminum panels used for the treatments were treated with TC-333 by applying a 1-second spray from a 12 inch distance onto each panel and with QuickBayt® by applying 2 trigger pulls from a 12 inch distance onto each panel. The treated panels were aged under ambient laboratory conditions and evaluated at 2 hours after application. One hundred flies were released inside each cage (2 ft by 2 ft screened cage, 4 replicates per treatment). After a 1 hour acclimation period, the test substance/panel and food were added to the cage. The food source (10% sucrose soaked cotton swabs) was placed on the floor in the cage. The total number of live, knocked down, and dead flies inside the cage was recorded at 1 hr, 2 hrs, 4 hrs, 24 hours, and daily as needed. The replicates were terminated after the evaluations were deemed complete and any remaining flies were removed from the cage prior to the start of a new replicate. The treated panel and the food source locations were rotated between each replicate.

Greater than 90% mortality was reached by 2 days for TC-333 (2HPTone Ver 2.0a), and by 3 days for TC-333 (BAS 395 KC I) and QuickBayt. Control mortality was acceptable through 3 days after treatment.
(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials: The data show that the product kills house flies three days after treatment when product is applied to a non-porous surface. Although the study stated that knockdown was recorded, no data was reported on this parameter. Note that the two formulations used are equivalent to the basic and alternate formulations of the proposed product.
(4) Is the study acceptable or not? Acceptable

49155110
(1) GLP or non-GLP? Non-GLP
(2) State the purpose and briefly summarize the methods and results: A study was conducted to determine the efficacy of TC-333 (BAS 395 KCI) compared with QuickBayt on house flies at animal confinement facilities under field conditions in Central California. Test sites were not treated with insecticides for approximately one week prior to treatment and all pest control was suspended in the treatment areas for the duration of the study. Pretreatment fly counts were conducted using visual assessments in several locations on each of the facilities and "fly stick counts" in three locations on each facility. Pre-treatment fly counts were conducted one day prior to treatment. Each of the 3 facilities had five replicates of each bait randomly assigned to predetermined treatment/monitoring locations. All baits were applied within 2.6 ft^2 aluminum pans (12" width x 14" length x 4" sides). TC-333 Aerosol Fly Bait and QuickBayt were sprayed five times and weighed to determine an average weight delivered per test pan. The TC-333 Aerosol Fly Bait aerosol application was timed with a stop watch and averaged 9.9 g for a 15 second spray duration. Post-treatment fly counts were conducted by counting the number of dead adult house flies (visual and volumetric counts on test days 3, 7, 10, and 13) that were in each treatment pan for the liquid baits.

Average number of flies per pan for TC-333 ranged from 61 (Day 3) to 220.1 (Day 10); for QuickBayt, the average number of flies ranged from 36.9 (Day 7) to 140.4 (Day 10). The total number of dead flies for all three locations was 7166 for TC-333 and 4579 for QuickBayt.
(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials: The data show that the proposed product performs as well or better than the commercial standard. However, there was not enough information to quantitatively calculate efficacy. Note that the formulation used is equivalent to the basic formulation of the proposed product.
(4) Is the study acceptable or not? Supplemental

49155111
(1) GLP or non-GLP? Non-GLP
(2) State the purpose and briefly summarize the methods and results: A study was conducted to determine the efficacy of TC-333 Aerosol Fly Bait (BAS 395 KG I) and QuickBayt (EPA Reg # 11556-147) against house flies (*Musca domestica*). The TC-333 applications were conducted by applying a 1-second spray from a 12 inch distance

onto each panel. The QuickBayt® applications were conducted by applying 2 trigger pulls from a 12 inch distance onto each panel. The treated 5" x 7" aluminum panels were aged under ambient laboratory conditions for 1 day, and 1, 2, 3, and 4 weeks. One hundred flies per each of 4 replicates per treatment were released inside a 2 ft by 2 ft screened cage. After a 1 hour acclimation period, the test substance/panel and food were added into the cage. The total number of alive, knocked down, and dead flies inside the cage was recorded at 1 hr, 2 hrs, 4 hrs, 24 hours, and daily as needed. The replicates were terminated after the evaluations were deemed complete and any remaining flies were removed from the cage prior to the start of a new replicate. The treated panel and the food source locations were rotated between each replicate.

For TC-333, after 1 day of panel aging, maximum efficacy was 83% at 24 hours after exposure. After 1 week of panel aging, maximum efficacy was 85% at 48 hours after exposure. Greater than 90% mortality was reached for panels aged 2 and 3 weeks at 24 hours and 48 hours respectively. After 4 weeks of panel aging, maximum efficacy was 83% at 48 hours after exposure. QuickBayt performed comparably, and control mortality was acceptable throughout the study.

(3) State conclusions as they relate to study results following your review of the primary efficacy review and the study materials: The data submitted show acceptable mortality (>90%) for panels aged 2 and 3 weeks, but somewhat lower mortality for panels aged 1 day, 1 week, and 4 weeks. It is unknown how long the product would last in field conditions with flies contacting the bait throughout. Note that the formulation used is equivalent to the basic formulation of the proposed product.

(4) Is the study acceptable or not? Supplemental

III. RECOMMENDATIONS:

When considered together, the data submitted support the use of the product to kill house flies at the labeled rate.

Efficacy Labeling Recommendations:

1) On page 1, delete references to filth flies and flesh flies. Only houseflies were tested, and another species of filth fly and flesh flies were not tested; their inclusion on the label would require the submission of additional efficacy data.
2) Delete use of the product in bait stations. Products used in bait stations may have lower efficacy and therefore this type of use would require additional data for inclusion on the label.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE: **OCSPP 810.3500** - Premises Treatments
MRID:	**491551-08.** Donahue, W.A. Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions. March 26, 2012
DP BARCODE:	413112
DECISION NO:	480032
SUBMISSION NO:	936866
SPONSOR:	BASF Corporation - Pest Control Solutions Whitmire Micro-Gen Research Laboratories 3568 Tree Court Industrial Blvd. St. Louis, MO 63122
TESTING FACILITY:	Sierra Research Laboratories, Inc. P.O. Box 576886 5100 Parker Road Modesto, CA 95357-0632
STUDY DIRECTOR:	William A, Donahue, Jr. Sierra Research Laboratories, Inc.
SUBMITTER:	D. Thomas BASF Corporation
STUDY COMPLETED:	26/03/2013
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	"This study was NOT conducted in compliance with Good Laboratory Practice Standards as described by EPA (40 CFR Parts 160 and 792), and was never intended for that purpose."
TEST MATERIAL:	PRODUCT NAME: PT® Alpine® Pressurized Fly Bait EPA REGISTRATION NUMBER OR FILE SYMBOL:

499-LAI
ACTIVE INGREDIENT NAME: Dinotefuran
CHEMICAL NAME: N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine
A.I. %:: 1%
PC CODE: 044312
CAS NO.: Not reported
FORMULATION TYPE: Pressurized fly bait
PRODUCT APPLICATION RATE(S): **Area Treatment**: Light application at a rate of 2 ln ft /sec. from a distance of no further than 12 inches (30 cm). **Band Treatment**: Spray from no further than 6 in (15 cm) at a rate of 2 ln ft/sec. **Removable Bait Placements**: Apply on small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine at least 6 in long.
ACTIVE INGREDIENT APPLICATION RATE(S) g/m^2: NA

PROPOSED LABEL MARKETING CLAIMS: Kills flies for up to 30 days on non-porous surfaces...

STUDY REVIEW

Purpose: The objective of the study was to evaluate the efficacy of two experimental fly bait aerosol formulations, an industry standard (QuickBayt®), and an untreated control against caged adult house flies, *Musca domestica* (SRL Hilmar Strain).

MATERIALS AND METHODS

Test Location: Presumably at the location of the testing laboratory in Modesto, CA.

Test Materials:

1. TC-333 Fly Bait Aerosol, Lq-BUT, Formula Code: 237-094, Lab Code: 237-094, Date 05/17/2012, 1.0000% Dinotefuran, net weight: 16 oz, BAS 395 KBI

2. TC-333 Fly Bait Aerosol, 2HPTone, Formula Code: 237-093, Lab Code: 237-093, Date: 05/15/2012, 1.0000% Dinotefuran, net weight: 16 oz BAS KAI

3. QuickBayt® Spot Spray - Imidacloprid 10.0%, Muscalure; Z-9-Tricosene 0.1%, Lot # 5488000 JI022, Date: 8/25/2010

PT® Alpine® Pressurized Fly Bait contains 1% dinotefuran, the same active ingredient at the same concentration as the two experimental substances.

Test Species Name, Life Stage, Sex and Age: Adult house flies, *Musca domestica* (SRL Hilmar Strain).

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Fly baits were evaluated in 18"x 18'x 18' screen cages in the laboratory with an average of 103.1 adult SRL Hilnar field stain house flies. Water was provided in an 8 oz. plastic cup with paper towel inserted and a 10% sucrose solution contained in a 4 oz. glass container with cotton wick was also provided as an alternate food source. A paper towel square was placed in the bottom of each cage.

The experimental baits were poured on and spread out to cover one side of a 6"x 6" x1/8" fiberglass reinforced panel (FRP). The average amount of bait applied is listed in Table 1. Bait panels were allowed to dry horizontally in the laboratory for 2 hours, aided with a fan, but remained tacky to the touch throughout the test. Bait panels were attached to the rear wall of the test cages with wire. All flies were mechanically aspirated from the rearing cages, anesthetized with CO_2 in the aspirator, and then placed into the test cages. An average of 103.1 house flies per replicate. The flies were allowed to recover for 1 hour before bait panel placement and the start of the test. Controls were treated in a same manner as all treatments. The four (4) cages of test bait treatments and untreated controls were evaluated simultaneously for each run (a single replicate for each bait or UTC) for three days to determine cumulative mortality.

Table 1. Average amount of fly bait applied per panel. (n=3)

Panel #	Bait	avg. amount applied (g)
1	237-093 2HPTone.	3.30
2	237-094 Lq-BUT	2.76
3	QuickBayt	1.26

List the treatments including untreated control: See Table 1.

Number of replicates per treatment: 3 (as indicated in Table 2).

Number of individuals per replicate: 103.1 (average).

Length of exposure to treatment: Three days.

Were tested specimens transferred to clean containers? No.

Experimental conditions (state relative humidity, temperature, and photoperiod):
Laboratory temperature and humidity were recorded.

Data or endpoints collected/recorded: House flies were assessed for knockdown at 1 and 3 hours on day 0 and for mortality once daily for three (3) days post-treatment. Mortality was determined when the fly was not moving and all dead flies were removed from the test cage.

Data analysis: Total cumulative mortality over 3 days.

RESULTS

Raw data for each replicate were included in the report.

The experimental aerosol fly bait 237-093 2HPTone showed greater cumulative adult house fly mortality (93.5%) than the industry standard QuickBayt® which achieved 82.4% cumulative mortality over the three-day evaluations (Table 2). The untreated control group had 4.0% cumulative mortality.

Table 2. Total knockdown and mortality of house flies exposed to treated and untreated panels in 18 inch confinement cages in the laboratory. (n=3)

Dead flies removed post 24 hours.

	Knockdown(1, 3 hrs)/Mortality (post 24 hrs)			
Bait	237-093 2HPTone	237-094 Lq-BUT	QuickBayt	UTC
1 Hour KD	120	97	116	0
3 Hour KD	172	132	152	0
24 Hour	228	178	148	1
Day 2	46	46	75	5
Day 3	15	26	40	6
Total Mortality	289	250	263	12
Percent Mortality	93.5	81.4	82.4	4.0
Total # Flies	309	307	319	302

Study Author's Conclusions

Both experimental fly baits 237-093 2HPTone and 237-094 Lq-BUT outperformed the industry standard QuickBayt® Spot Spray at 24 hours of the test. The experimental aerosol fly bait 237-093 2HPTone showed the greatest cumulative adult house fly mortality, 93.5% over the three day evaluation period.

Reviewer's Conclusions

TC-333 Fly Bait Aerosol, 2HPTone provided an acceptable level of control (93.5%) after 3 days, but TC-333 Fly Bait Aerosol, Lq-BUT did not (81.4%). The test substances were poured onto the fiberglass reinforced panels whereas the label indicates that the product is an aerosol; therefore it cannot be determined if the amount applied under typical consumer use would be comparable. For TC-333 Fly Bait Aerosol, 2HPTone, percent knockdown after 3 hours was only 56% which may not fully support the label claim of "Quick Knockdown". Confined exposure of the flies for up to 3 days might not be considered a realistic duplication of exposures occurring under typical consumer use.

Reviewer's Recommendations

Unacceptable, the experimental protocol does not adequately duplicate use and exposures likely to occur during typical consumer use.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 491551-08. Donahue, W.A. Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions. March 26, 2013.

OCSPP 810.3500 - Premises Treatments

Product Name: PT® Alpine® Pressurized Fly Bait
EPA Reg. No. or File Symbol: 499-LAI
Decision number: 480032
DP number: 413112

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-143

Primary Reviewer:
Dennis M. Opresko, Ph.D.

Signature: Dennis M. Opresko DMO
Date: 08/11/2013

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess MG
Date: 08/11/2013

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross MG
Date: 08/11/2013

Quality Assurance:
Angela Edmonds, B.S.

Signature: Angela Edmonds
Date: 08/11/2013

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]_____

STUDY TYPE:	PRODUCT PERFORMANCE: **OCSPP 810.3500** - Premises Treatments
MRID:	**491551-09.** E. Snell, et al. Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*). March 9, 2013.
DP BARCODE:	413112
DECISION NO:	480032
SUBMISSION NO:	936866
SPONSOR:	BASF Corporation - Pest Control Solutions Whitmire Micro-Gen Research Laboratories 3568 Tree Court Industrial Blvd. St. Louis, MO 63122
TESTING FACILITY:	Snell Scientifics, LLC 188 Vega Road Meansville, GA. 30256
STUDY DIRECTOR:	Todd Smith Snell Scientifics, LLC.
SUBMITTER:	D. Thomas BASF Corporation
STUDY COMPLETED:	09/03/2013
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	"This study was NOT conducted in compliance with Good Laboratory Practice Standards as described by EPA (40 CFR Parts 160 and 792), and was never intended for that purpose."
TEST MATERIAL:	PRODUCT NAME: PT® Alpine® Pressurized Fly Bait EPA REGISTRATION NUMBER OR FILE SYMBOL: 499-LAI ACTIVE INGREDIENT NAME: Dinotefuran

CHEMICAL NAME: N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine
A.I. %:: 1%
PC CODE: 044312
CAS NO.: Not reported
FORMULATION TYPE: Pressurized fly bait
PRODUCT APPLICATION RATE(S): **Area Treatment**: Light application at a rate of 2 ln ft /sec. from a distance of no further than 12 inches (30 cm). **Band Treatment**: Spray from no further than 6 in (15 cm) at a rate of 2 ln ft/sec. **Removable Bait Placements**: Apply on small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine at least 6 in long.
ACTIVE INGREDIENT APPLICATION RATE(S) g/m^2: NA

PROPOSED LABEL MARKETING CLAIMS: Kills flies for up to 30 days on non-porous surfaces…

STUDY REVIEW

Purpose: To determine the efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against house flies (*Musca domestica*).

MATERIALS AND METHODS

Test Location: Presumably at the location of the testing laboratory. Meansville, GA

Test Materials:

1. Controls - Untreated
2. TC-333 Aerosol Fly Bait BAS 395 KC I (1.00% Dinotefuran), EPA Est. No. 7969-MO-l, (Snell Codes: 012113-1-B-BAS through 012113-2-B-BAS)
3. TC-333 Fly Bait Aerosol 2HPTone Ver 2.0a BAS 395 KC I (1.0000% Dinotefuran), Formula code: 243-006, Lab code: 243-008 BAS395 KEI, (Snell Codes: 012113-3-B-BAS through 012113-4-B-BAS)
4. QuickBayt® Spot Spray (10.0% Imidacloprid, 0.1% Z-9-Tricosene), 5488004 NT98CX5009 AB027, EPA Reg. No. 11556-147, (Snell Code: 100112-1-B-SNE).

PT® Alpine® Pressurized Fly Bait contains 1% dinotefuran, the same active ingredient at the same concentration as the two experimental substances.

Test Species Name, Life Stage, Sex and Age: Adult house flies (*Musca domestica*).

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: The 5" x 7" aluminum panels used for the treatments were treated using the following methods. The TC-333 applications were conducted by applying a 1-second spray from a 12 inch distance onto each panel. The QuickBayt® applications were conducted by applying 2 trigger pulls from a 12 inch distance onto each panel. The treated panels were aged under ambient laboratory conditions and evaluated at 2 hours after applications. The incandescent light inside the test room was turned "on" during the tests. The flies were sorted from the rearing containers into groups of 100 per holding container. All of the flies were confirmed to be of "good vigor" (alive) prior to testing. Only live flies were selected for use in the study. They were confirmed to be alive and exhibiting normal behavior before continuing with the study. During sorting, the flies were counted to ensure that the exact number was collected for testing. The flies were allowed to recover from anesthetizing prior to releasing in the cage. 100 flies were released inside the cage (2 ft by 2 ft screened cage). After a 1 hour acclimation period, the test substance/panel and food was added into the cage. One panel was placed on a ~3" high plastic cup on the floor in the center of the cage. The cup was inverted so that the open side was on the floor. The food source (10% sucrose soaked cotton swabs) was placed on the floor in the cage. The total number of "Alive", "Knock Down (KD)", and "Dead" flies inside the cage was recorded at 1 hr, 2 hrs, 4 hrs, 24 hours, and daily as needed. The replicates were terminated after the evaluations were deemed complete and any remaining flies were removed from the cage prior to the start of a new replicate. The treated panel and the food source locations were rotated between each replicate.

List the treatments including untreated control: A 1-second spray of TC-333 from a 12 inch distance.

Number of replicates per treatment: 4

Number of individuals per replicate: 100

Length of exposure to treatment: Five days.

Were tested specimens transferred to clean containers? No.

Experimental conditions (state relative humidity, temperature, and photoperiod):
Application: temperature: 38°F; humidity: 48%.

Data or endpoints collected/recorded: Total number of "Alive", "Knock Down (KD)", and "Dead" flies recorded at 1 hr, 2 hrs, 4 hrs, 24 hours, and daily as needed.

Data analysis: Average percent mortality was calculated. In addition, the mortality rates that were recorded were statistically analyzed using two different t tests for independent samples. The first analysis was conducted using a one-tailed distribution and probability value of $p<0.05$ to evaluate if any significant differences in mortality were recorded between the controls and the test substances. The second analysis was conducted using a two-tailed distribution and probability value of $p<0.05$.

RESULTS

Raw data were not included in the report. Results are shown in Table 1.

Similar mortality rates were recorded between all three test substances during the study, with all three formulations recording >87% mortality within 2 days after exposure to the treatments. Significant differences were recorded between the mortality rates of the specimens that were exposed to the three treatments (both TC-333 formulations and QuickBayt®) and the un-treated controls from the 1 hour observations onward.

Table 1.

House Fly (*Musca domestica*)									
Average % Mortality									
Test Substance:	**Pre-trt**	**1 hr**	**2 hr**	**4 hr**	**24 hr**	**2 DAT**	**3 DAT**	**4 DAT**	**5 DAT**
Controls - Untreated	0%	0%	1%	1%	3%	4%	9%	54%	78%
TC-333 Aerosol Fly Bait BAS 395 KC I	0%	10%	13%	22%	71%	87%	93%	98%	99%
TC-333 Fly Bait Aerosol 2HPTone Ver 2.0a	0%	8%	11%	19%	79%	96%	98%	99%	99%
Quick Bayt Spot Spray	0%	8%	14%	21%	63%	88%	95%	99%	99%

Study Author's Conclusions

The results of the study indicate that, applications of TC-333 Aerosol Fly Bait BAS.395 KC I (1.00% Dinotefuran) and TC-333 Fly Bait Aerosol 2HPTone Ver 2.0a BAS 395 KC I (1.0000% Dinotefuran) provide similar results against house flies (*Musca domestica*), with each formulation proving comparable to QuickBayt® Spot Spray (10.0% Imidacloprid, 0.1% Z-9-Tricosene).

Reviewer's Conclusions

Average percent mortality was >90% for both TC-333 formulations at 3 DAT.

Reviewer's Recommendations

Supports the conclusion that the test products kill house flies after 3 days of exposure to treated aluminum surfaces, assuming a 3-day confinement of flies in a 2 by 2 ft cage is not considered an excessive exposure when compared to exposures that might occur under typical consumer use. Does not support the label claims of "Quick Knockdown" or 30 day control.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 491551-09. E. Snell, et al. Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*). March 9, 2013.

OCSPP 810.3500 - Premises Treatments

Product Name: PT® Alpine® Pressurized Fly Bait
EPA Reg. No. or File Symbol: 499-LAI
Decision number: 480032
DP number: 413112

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-143

Primary Reviewer:
Dennis M. Opresko, Ph.D.

Signature: Dennis M. Opresko AS
Date: 08/11/2013

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess AB
Date: 08/11/2013

Robert H. Ross, M.S., Program Manager

Signature: Robert H Ross AC
Date: 08/11/2013

Quality Assurance:
Angela Edmonds, B.S.

Signature: Angela Edmonds
Date: 08/11/2013

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE: **OCSPP 810.3500 -** Premises Treatments
MRID:	**491551-10.** Donahue, W.A. Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica* on Animal Confinement Facilities in Central California. Feb. 19, 2013.
DP BARCODE:	413112
DECISION NO:	480032
SUBMISSION NO:	936866
SPONSOR:	BASF Corporation - Pest Control Solutions Whitmire Micro-Gen Research Laboratories 3568 Tree Court Industrial Blvd. St. Louis, MO 63122
TESTING FACILITY:	Sierra Research Laboratories, Inc. P.O. Box 576886 5100 Parker Road Modesto, CA 95357-0632
STUDY DIRECTOR:	William A, Donahue, Jr. Sierra Research Laboratories, Inc.
SUBMITTER:	D. Thomas BASF Corporation
STUDY COMPLETED:	19/02/2013
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	"This study was NOT conducted in compliance with Good Laboratory Practice Standards as described by EPA (40 CFR Parts 160 and 792), and was never intended for that purpose."

TEST MATERIAL:	PRODUCT NAME: PT® Alpine® Pressurized Fly Bait EPA REGISTRATION NUMBER OR FILE SYMBOL: 499-LAI ACTIVE INGREDIENT NAME: Dinotefuran CHEMICAL NAME: N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine A.I. %:: 1% PC CODE: 044312 CAS NO.: Not reported FORMULATION TYPE: Pressurized fly bait PRODUCT APPLICATION RATE(S): **Area Treatment**: Light application at a rate of 2 ln ft /sec. from a distance of no further than 12 inches (30 cm). **Band Treatment**: Spray from no further than 6 in (15 cm) at a rate of 2 ln ft/sec. **Removable Bait Placements**: Apply on small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine at least 6 in long. ACTIVE INGREDIENT APPLICATION RATE(S) g/m^2: NA.
PROPOSED LABEL MARKETING CLAIMS:	Kills flies for up to 30 days on non-porous surfaces…

STUDY REVIEW

Purpose: To determine the efficacy (mortality) of an aerosol/liquid fly bait formulation compared with a commercial standard on animal confinement facilities under field conditions in Central California.

MATERIALS AND METHODS

Test Location: Three animal confinement facilities located in Modesto, CA:

1) Peder Hoy Dairy, 6042 California Ave. Modesto, CA 95358
2) Rocking S Dairy #2, 2352 Ladd Rd., Modesto, CA 95356
3) Modesto Jr. College West Campus, 22201 Blue Gum Rd., Modesto, CA 95350.

Test Materials:

1. TC-333 Aerosol Fly Bait, BAS 395 KCI; EPA Est. No. 7969-MO-l; 1.00% Dinotefuran

2. QuickBayt® Spot Spray - Imidacloprid 10.0%,Muscalure; Z-9-Tricosene 0.1%, Lot# 5488000 JI022, Date: 8/25/2010

PT® Alpine® Pressurized Fly Bait contains 1% dinotefuran, the same active ingredient at the same concentration as that in TC-333.

Test Species Name, Life Stage, Sex and Age: House flies, *Musca domestica*, endemic populations located on two types of animal confinement facilities (dairies and beef cattle feed lots) near Modesto, CA (Stanislaus Co).

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: Test sites were not treated with insecticides for approximately one week prior to treatment and all pest control was suspended in the treatment areas for the duration of the study. Pretreatment fly counts were conducted using visual assessments in several locations on each of the facilities and "fly stick counts" in three locations on each facility. Pre-treatment fly counts were conducted one (1) day prior to treatment. Each of the facilities had five replicates of each bait randomly assigned to predetermined treatment/monitoring locations

All baits were applied within 2.6 ft^2 aluminum pans (12" width x 14" length x 4" sides) and labeled as per treatment, facility and location. The TC-333 Aerosol Fly Bait and QuickBayt was sprayed five times and weighed to determine an average weight delivered per test pan. The TC-333 Aerosol Fly Bait aerosol application was timed with a stop watch and averaged 9.9 g for a 15 second spray duration.

Post-treatment fly counts were conducted by counting the number of dead adult house flies (visual and volumetric counts on test days 3, 7, 10, and 13) that are in each treatment pan for the liquid baits.

List the treatments including untreated control: Average of 9.9 g of TC-333 per pan.

Number of replicates per treatment: 5 at each facility.

Number of individuals per replicate: NA.

Length of exposure to treatment:. NA.

Were tested specimens transferred to clean containers? NA.

Experimental conditions (state relative humidity, temperature, and photoperiod): Environmental conditions (temperature, humidity, wind, weather) were reported for each test day from CIMIS weather data for Modesto, CA, San Joaquin Valley, Station 7.

Data or endpoints collected/recorded:. Number of dead adult house flies (visual and volumetric counts on test days 3, 7, 10, and 13) that were in each treatment pan for the three liquid baits.

Data analysis: Comparison of the two test substances, but no statistical analysis.

RESULTS

Results for all sites combined is shown in Table 1.

Table 1. Fly Counts per Pan across all Test Sites

	Avg. # of Flies per Pan per Treatment			
Treatment	Day 3	Day 7	Day 10	Day 13
TC-333	61.0	74.3	220.1	133.8
QuickBayt	75.8	36.9	140.4	62.2

TC-333 showed the highest average number of dead flies collected on test day 13 with 133.8 per treatment pan and the lowest average number of dead flies with 61.0 per treatment pan on test day 3.

Study Author's Conclusions

Based on total dead fly counts for all test sites and replicates the descending order of activity of the liquid fly baits was TC-333 > QuickBayt®.

Reviewer's Conclusions

Although the data indicate that TC-333 is as effective at reducing fly numbers under the conditions tested at a level similar to that of QuickBayt®; there is insufficient quantitative data to assess overall efficacy in terms of percent control.

Reviewer's Recommendations

Provisionally acceptable in that the test product performed as well as QuickBayt®. Supports a label statement that the product aids in the control of flies in dairy and beef cattle confinement facilities.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 491551-10. Donahue, W.A. Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica* on Animal Confinement Facilities in Central California. Feb. 19, 2013.

OCSPP 810.3500 - Premises Treatments

Product Name: PT® Alpine® Pressurized Fly Bait
EPA Reg. No. or File Symbol: 499-LAI
Decision number: 480032
DP number: 413112

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-143

Primary Reviewer:
Dennis M. Opresko, Ph.D.

Signature: Dennis M. Opresko
Date: 08/11/2013

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess
Date: 08/11/2013

Robert H. Ross, M.S. Program Manager

Signature: Robert H Ross
Date: 08/11/2013

Quality Assurance:
Angela Edmonds, B.S.

Signature: Angela Edmonds
Date: 08/11/2013

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

DATA EVALUATION RECORD

[EPA Primary Reviewer's Name]

STUDY TYPE:	PRODUCT PERFORMANCE: **OCSPP 810.3500** - Premises Treatments
MRID:	**491551-11.** Snell, E. et al. Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*). Nov. 16, 2012.
DP BARCODE:	413112
DECISION NO:	480032
SUBMISSION NO:	936866
SPONSOR:	BASF Corporation - Pest Control Solutions Whitmire Micro-Gen Research Laboratories 3568 Tree Court Industrial Blvd. St. Louis, MO 63122
TESTING FACILITY:	Snell Scientifics, LLC 188 Vega Road Meansville, GA. 30256
STUDY DIRECTOR:	Todd Smith Snell Scientifics, LLC.
SUBMITTER:	D. Thomas BASF Corporation
STUDY COMPLETED:	16/11/2012
CONFIDENTIALITY CLAIMS:	None
GOOD LABORATORY PRACTICE:	"This study was NOT conducted in compliance with Good Laboratory Practice Standards as described by EPA (40 CFR Parts 160 and 792), and was never intended for that purpose."
TEST MATERIAL:	PRODUCT NAME: PT® Alpine® Pressurized Fly Bait EPA REGISTRATION NUMBER OR FILE SYMBOL: 499-LAI ACTIVE INGREDIENT NAME: Dinotefuran

CHEMICAL NAME: N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine
A.I. %:: 1%
PC CODE: 044312
CAS NO.: Not reported
FORMULATION TYPE: Pressurized fly bait
PRODUCT APPLICATION RATE(S): **Area Treatment**: Light application at a rate of 2 ln ft /sec. from a distance of no further than 12 inches (30 cm). **Band Treatment**: Spray from no further than 6 in (15 cm) at a rate of 2 ln ft/sec. **Removable Bait Placements**: Apply on small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine at least 6 in long.
ACTIVE INGREDIENT APPLICATION RATE(S) g/m^2: NA

PROPOSED LABEL MARKETING CLAIMS: Kills flies for up to 30 days on non-porous surfaces…

STUDY REVIEW

Purpose: To determine the efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against house flies (*Musca domestica*).

MATERIALS AND METHODS

Test Location: Presumably at the location of the testing laboratory. Mcansville, GA

Test Materials:

1. Controls - Untreated
2. TC-333 Aerosol Fly Bait BAS 395 KG I (1.00% Dinotefuran), (Snell Codes: 091012-1-B-BAS through 091012-6-B-BAS)
3. QuickBayt® Spot Spray (10.0% Imidacloprid, 0.1% Z-9-Tricosene), 5488004 NT98CX:5009 AB027, EPA Reg. No. 11556-147, (Snell Code: 100112-1-B-SNE)

PT® Alpine® Pressurized Fly Bait contains 1% dinotefuran, the same active ingredient at the same concentration as the two experimental substances.

Test Species Name, Life Stage, Sex and Age: Adult house flies (*Musca domestica*).

Describe test containers, chambers and/or apparatus (include site description and location) and how experiment was conducted: The 5" x 7" aluminum panels used for the treatments were treated using the following methods. The TC-333 applications were conducted by applying a 1-second spray from a 12 inch distance onto each panel. The QuickBayt® applications were

conducted by applying 2 trigger pulls from a 12 inch distance onto each panel. The treated panels were aged under ambient laboratory conditions and evaluated at 1 DAT (Day After Treatment), and at 1, 2, 3, and 4 WAT (Weeks After Treatment).

The incandescent light inside the test room was turned on during the tests. The flies were sorted from the rearing containers into groups of 100 per holding container. All the flies were confirmed to be alive and exhibiting normal behavior before continuing with the study. During sorting, the flies were counted to ensure that the exact number was collected for testing. The flies were allowed to recover from anesthetizing prior to releasing in the cage. 100 flies were released inside the cage (2 ft by 2 ft screened cage). After a 1 hour acclimation period, the test substance/panel and food was added into the cage. One panel was placed on a ~3" high plastic cup on the floor in the center of the cage. The cup was inverted so that the open side was on the floor. The food source (10% sucrose soaked cotton swabs) was placed on the floor in the cage. The total number of "Alive", "Knock Down (KD)", and "Dead" flies inside the cage was recorded at 1 hr, 2 hrs, 4 hrs, 24 hours, and daily as needed. The replicates were terminated after the evaluations were deemed complete and any remaining flies were removed from the cage prior to the start of a new replicate. The treated panel and the food source locations were rotated between each replicate.

List the treatments including untreated control: A 1-second spray of TC-333 from a 12 inch distance.

Number of replicates per treatment: 4

Number of individuals per replicate: 100

Length of exposure to treatment: Up to 3 days.

Were tested specimens transferred to clean containers? No.

Experimental conditions (state relative humidity, temperature, and photoperiod): Application: temperature: 71°F; humidity: 57%.

Data or endpoints collected/recorded: Total number of "Alive", "Knock Down (KD)", and "Dead" flies recorded at 1 hr, 2 hrs, 4 hrs, 24 hours, and daily as needed.

Data analysis: Average percent mortality was calculated. In addition to the percent mortality calculations, the mortality rates that were recorded were statistically analyzed using two different t tests for independent samples. The first analysis was conducted using a one-tailed distribution and probability value of $p<0.05$ to evaluate if any significant differences in mortality were recorded between the controls and the test substances. The second analysis was conducted using a two-tailed distribution and probability value of $p<0.05$ to evaluate if any significant differences in mortality were recorded between each of the test substances.

RESULTS

Raw data were not included in the report. Results are shown in Table 1. Mortality of untreated controls was within acceptable limits. Panels treated with TC-333 resulted in >83% mortality for all 5 aging times, with the two and three week evaluations resulting in 100% mortality.

Table 1.

House Fly (*Musca domestica*) Average % Mortality								
Aged Evaluation:	Test Substance:	Pre-trt	1 hr	2 hr	4 hr	24 hr	2 DAT	3 DAT
1 Day	Control - Un-treated	0%	0%	0%	0%	2%	N/A	N/A
	TC-333 Aerosol Fly Bait	0%	6%	10%	20%	83%	N/A	N/A
	QuickBayt Spot Spray	0%	11%	18%	21%	72%	N/A	N/A
1 Week	Control - Un-treated	0%	0%	0%	0%	2%	2%	N/A
	TC-333 Aerosol Fly Bait	0%	6%	10%	20%	83%	85%	N/A
	QuickBayt Spot Spray	0%	3%	3%	3%	50%	71%	N/A
2 Week	Control - Un-treated	0%	0%	0%	2%	4%	3%	4%
	TC-333 Aerosol Fly Bait	0%	57%	68%	84%	91%	100%	100%
	QuickBayt Spot Spray	0%	34%	55%	66%	77%	92%	96%
3 Week	Control - Un-treated	0%	0%	1%	2%	4%	6%	6%
	TC-333 Aerosol Fly Bait	0%	3%	6%	17%	78%	92%	100%
	QuickBayt Spot Spray	0%	3%	3%	3%	50%	71%	94%
4 Week	Control - Un-treated	0%	0%	0%	2%	4%	6%	N/A
	TC-333 Aerosol Fly Bait	0%	21%	43%	61%	74%	83%	N/A
	QuickBayt Spot Spray	0%	19%	28%	48%	69%	80%	N/A

Study Author's Conclusions

Based on the results of the study, applications of TC-333 Aerosol Fly Bait BAS 395 KC I (1.00% Dinotefuran) prove to be effective against house flies (*Musca domestica*) for up to 4 weeks after application.

Reviewer's Conclusions

Results for TC-333 were inconsistent. Adequate levels of control (>90% mortality) were seen only at 24 hr, 2 DAT, and 3 DAT for panels aged 2 weeks and at 2 DAT and 3 DAT with panels aged for 3 weeks. Confinement of flies in the exposure cages for up to 3 DAT may not realistically duplicate conditions of exposure under normal consumer use.

Reviewer's Recommendations

Results are inconsistent and could only be used to support a label statement that the product aids in the control of house flies, assuming that continuous confinement of flies in a 2 ft by 2 ft exposure cage for up to 3 days is not considered an excessive exposure when compared to exposures that might occur under typical consumer use. Does not support the label claims of "Quick Knockdown" or 30 day control.

TASK 2 DATA EVALUATION RECORD

STUDY TYPE: Product Performance

MRID 491551-11. Snell, E. et al. Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*). Nov. 16, 2012.

OCSPP 810.3500 - Premises Treatments

Product Name: PT® Alpine® Pressurized Fly Bait
EPA Reg. No. or File Symbol: 499-LAI
Decision number: 480032
DP number: 413112

Prepared for
Registration Division (7505)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, DC 20460

Prepared by
Summitec Corporation
Task Order No.: 2-143

Primary Reviewer:
Dennis M. Opresko, Ph.D.

Signature: Dennis M. Opresko AG
Date: 08/11/2013

Secondary Reviewers:
Gene Burgess, Ph.D.

Signature: Gene Burgess AG
Date: 08/11/2013

Robert H. Ross, M.S. Program Manager

Signature: Robert H. Ross AG
Date: 08/11/2013

Quality Assurance:
Angela Edmonds, B.S.

Signature: Angela Edmonds
Date: 08/11/2013

Disclaimer

This review may have been altered subsequent to the contractors' signatures above.
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No. EP-W-11-014

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

17/DEC/2013

MEMORANDUM

Subject: Acute Toxicity Review for EPA File Symbol 499-LAI

Name of Pesticide Product:	PT Alpine Pressurized Fly Bait
EPA File Symbol:	499-LAI
DP Barcode:	D413111
Decision No.:	480032
Action Code:	R310
PC Code:	044312 (dinotefuran)

From: Eugenia McAndrew, Biologist
Technical Review Branch
Registration Division (7505P)

E. McAndrew

M Hopkins
T.L. Toxicology

To: Rita Kumar, RM Team 07
Insecticide-Rodenticide Branch
Registration Division (7505P)

Applicant: Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Ind. Blvd.
St. Louis, MO 63122

FORMULAIION FROM LABEL:

Active Ingredient(s):	% by wt.
Dinotefuran	1.0
Other Ingredient(s):	99.0
Total:	100.0%

ACTION REQUESTED: The Risk Manager requests a review of six acute toxicity studies submitted to support registration of the proposed product, EPA File Symbol 499-LAI.

BACKGROUND: Whitmire Micro-Gen Research Laboratories, Inc. has submitted six acute toxicity studies (MRID Nos. 491551-02 to -07) to support the registration of the proposed product, PT Alpine Pressurized Fly Bait, EPA File Symbol 499-LAI. The submission also includes a basic CSF and Alternate # 1 CSF dated June 12, 2013 which must be reviewed and accepted by the TRB Product Chemistry Team.

In a letter dated April 29, 2013, the registrant states that PT Alpine Pressurized Fly Bait is the planned marketplace name. In the studies submitted for review, the product is identified by its project development tracking code, TC-333, and experimental formulation numbers BAS 395 KC I and BAS 395 KE I.

GLP: Yes

DEVIATIONS: None

LABELING:

PRODUCT ID #: 499-00568

PRODUCT NAME: PT Alpine Pressurized Fly Bait

PRECAUTIONARY STATEMENTS

SIGNAL WORD: (optional) CAUTION

Hazards to Humans and Domestic Animals:

First Aid: No statements are required. Category III statements may be used.

DATA EVALUATION RECORD

Product Reg. No.: 499-LAI
Product Name: PT Alpine Pressurized Fly Bait

1. DP BARCODE: 413111

2. PC CODE: 044312

3. CURRENT DATE: December 17, 2013

4. TEST MATERIAL: TC-333 (Formula BAS 395 KC 1 / FC 237-199; target 1.0% dinotefuran, actual 0.9640%; density - 0.997 g/mL; pH 8.71; clear liquid with an odor of acetone received in a pressurized can; The aerosol can was shaken and inverted so the bottom was upright. The bottom was cleaned and the can left undisturbed for several minutes to allow the liquid inside to drain from the inner surface of the bottom of the can. A hole was made in the bottom of the can and the sample was drained into a separate container. The recovered liquid was administered.)

Primary eye irritation study: The test substance was received in a pressurized aerosol can. The right eye of each rabbit was held open and the test substance was administered in a single burst for approximately one second at a distance of about 10 cm, directly into the eye. Each animal received a dose of approximately 0.3-0.5 grams of the test substance.

Study/Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity / rat Product Safety Labs Study #35511/December12, 2012 OCSPP 870.1100; OECD 425	49155102	LD_{50} Females > 5000 mg/kg no clinical signs observed; no gross abnormalities at necropsy; body weight gains	IV	A
Acute dermal toxicity / rat Product Safety Labs Study #35512/December 13, 2012 OCSPP 870.1200; OECD 402	49155103	LD_{50} > 5000 mg/kg (both sexes) no clinical signs observed; no dermal irritation; mechanical damage around 5 dose sites due to unwrapping; 8/10 animals lost weight by day 7 but all animals gained weight by day 14; no gross abnormalities at necropsy	IV	A
Acute inhalation toxicity / rat Product Safety Labs Study #35513/December 14, 2012 OCSPP 870.1300; OECD 403	49155104	LC_{50} > 5.09 mg/L (both sexes) MMAD: 1.94, 1.88 µm GSD: 2.15, 2.12 clinical signs: irregular respiration in all animals with recovery by day	IV	A

		2; all animals lost weight by day 1 but gained weight thereafter; no gross abnormalities at necropsy		
Primary eye irritation / rabbit Product Safety Labs Study #35514/December 14, 2012 OCSPP 870.2400; OECD 405	49155105	3 females tested ocular anesthetic used no corneal opacity, iritis or positive scores for conjunctivitis; score of 1 for redness in 1eye at 1 hr; all eyes clear by 24 hrs	IV	A
Primary dermal irritation / rabbit Product Safety Labs Study #35515/December 12, 2012 OCSPP 870.2500; OECD 404	49155106	2 males and 1 female tested PDI = 0.0 no dermal irritation observed	IV	A
Dermal sensitization / guinea pig Product Safety Labs Study #35516/December 14, 2012 OCSPP 870.2600; OECD 406	49155107	Is *not* a sensitizer appropriate positive control provided	--	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap

Kumar, Rita

Resubmission; 5947570

From: Dana M Thomas [dana.thomas@basf.com]
Sent: Monday, August 12, 2013 10:11 AM
To: Kumar, Rita
Subject: 499-LAI; PT® Alpine® Pressurized Fly Bait
Attachments: 000499-00LAI.20130808.Mitsui LOA.PT Alpine Press Fly Bait.pdf

Good morning, Rita.

Attached is the LOA from Mitsui. Please confirm receipt.

Kind regards,
-Dana
Dana M. Thomas
Product Regulatory Mgr.
Authorized Agent for Whitmire Micro-Gen Researh Laboratories, Inc.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions

Mitsui Chemicals Group

MITSUI CHEMICALS AGRO, INC.

REGISTRATION & REGULATORY AFFAIRS DEPARTMENT
1-5-2, Higashi-Shimbashi, Minato-ku, Tokyo 105-7117, Japan
Telephone: +81-3-3573-9677 Facsimile: +81-3-3573-9898

August 8, 2013

Mrs. Rita Kumar
Insecticide Branch
Registration Division
Office of Pesticide Programs (7505P)
One Potomac Yard (South Building)
2777 S. Crystal Drive, Arlington, VA 22202

Re: Letter of Access for Data Reference
Whitmire Micro-Gen Research Laboratories, Inc.
PT® Alpine® Pressurized Fly Bait (EPA Reg. No. 499-XXX)

Dear Ms. Kumar,

We, Mitsui Chemicals Agro, Inc. (hereinafter referred to as "MCAG"), hereby state that the data owned by MCAG in support of the registration of the pesticide technical material dinotefuran, may be referred to by the EPA and its contractors in order to grant registration of indoor / outdoor commercial and residential uses of PT® Alpine® Pressurized Fly Bait (EPA Reg. No. 499-XXX) to:

Whitmire Micro-Gen Research Laboratories, Inc. (hereinafter referred to as "Whitmire")
3568 Tree Court Industrial Blvd.
St. Louis MO 63122-6682

This Letter of Access is specific for the active ingredient dinotefuran. The right to refer to the data is subject to the following restrictions:

1. The right of referral only gives access to the data of dinotefuran technical to support the registration of indoor/outdoor commercial and residential uses of PT® Alpine® Pressurized Fly Bait.
2. The right of referral is only valid for dinotefuran pesticide or origin from MCAG.
3. The right of referral only gives access for the registration of dinotefuran.
4. The right of referral is solely granted to WHITMIRE and is not transferable to any further companies or other legal or natural entities.
5. The right of referral is only valid for the registration of PT® Alpine® Pressurized Fly Bait.
6. The right of referral does not imply MCAG approval for any future WHITMIRE registrations.
7. MCAG retains the right to revoke this Letter of Access at any time or after termination of the agreement with WHITMIRE.

This letter of access for data reference covers registrations issued to Whitmire Micro-Gen Research Laboratories, Inc. a wholly owned subsidiary of BASF Corporation, but retains its own name.

Submitted by: Mitsui Chemicals Agro, Inc.

Authorized Signature: _____

Kazutomi Ohnuma
Executive Officer, General Manager
Executive Officer, Deputy Director of Research and Development Division
Director, Registration & Regulatory Affairs Department
Mitsui Chemicals Agro, Inc.

Kumar, Rita

From: Dana M Thomas [dana.thomas@basf.com]
Sent: Friday, July 12, 2013 6:09 PM
To: Kumar, Rita
Cc: Hebert, John
Subject: RE: New product application 499-LAI

Rita,

My apologies. I knew it was the first listed efficacy study on the Transmittal Document, but I must have looked in the wrong section and grabbed the first listed study/MRID for tox.

The correct answer is MRID 49155108.

Have a good weekend.

Kind regards,
-Dana
Dana M. Thomas
Product Regulatory Mgr.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Dana M Thomas <dana.thomas@basf.com>
Cc: "Hebert, John" <Hebert.John@epa.gov>
Date: 07/12/2013 03:49 PM
Subject: RE: New product application 499-LAI

This MRID # is for the acute oral toxicity study. Your cover letter states that one of the efficacy studies is done on a slightly formulation. Please resolve the discrepancy.

Rita

From: Dana M Thomas [mailto:dana.thomas@basf.com]
Sent: Monday, July 01, 2013 3:49 PM
To: Kumar, Rita
Cc: Hebert, John
Subject: Fw: New product application 499-LAI

Hi Rita,

The MRID number you requested in comment #3 is: MRID No. 49155102

Kumar, Rita

From: Kumar, Rita
Sent: Friday, July 12, 2013 4:49 PM
To: 'Dana M Thomas'
Cc: Hebert, John
Subject: RE: New product application 499-LAI

This MRID # is for the acute oral toxicity study. Your cover letter states that one of the efficacy studies is done on a slightly formulation. Please resolve the discrepancy.

Rita

From: Dana M Thomas [mailto:dana.thomas@basf.com]
Sent: Monday, July 01, 2013 3:49 PM
To: Kumar, Rita
Cc: Hebert, John
Subject: Fw: New product application 499-LAI

Hi Rita,

The MRID number you requested in comment #3 is: MRID No. 49155102

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions
----- Forwarded by Dana M Thomas/BASF-CORP/BASF on 07/01/2013 02:40 PM -----

From: Dana M Thomas/BASF-CORP/BASF
To: "Kumar, Rita" <Kumar.Rita@epa.gov>
Cc: "Hebert, John" <Hebert.John@epa.gov>
Date: 06/28/2013 04:19 PM
Subject: Re: New product application 499-LAI

Resubmission
S; 945769

Rita,

In response to your questions:

1. I have requested a LoA from Mitsui and will supply it to you as soon as I receive it.

2. The Basic CSF only has 1 page (attached is revised Basic reflecting Page 1 of 1).

3. I cannot provide you with the MRID for the efficacy study as requested, because I have yet to receive that information from the Agency. The only correspondence I've received from the Agency so far is the Receipt of Application, dated 6/19/13 (attached for reference). I will provide the requested MRID to you as soon as I receive it. However, if you look at the Transmittal Document, it is the 1st listed study under Product Performance, titled

"Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions; Sierra Research Laboratories, Inc., Laboratory Project ID: #BAS12-1-SS / BASF DIMeS #2005 / RAS #3397".

4. I supplied the MSDSs or SDSs for all of the ingredients because after years of not having done so, I was required to submit them on more than one occasion, so I thought it best to include them. Can you please clarify this for me if this is a requirement?

Kind regards,
Dana M. Thomas
Product Regulatory Mgr.

Phone: 636-861-4223, Fax: 636-225-3739, E-Mail: dana.thomas@basf.com
Postal Address: BASF Corporation, 3568 Tree Court Ind. Blvd., St. Louis, MO 63122-6682 St. Louis, USA

BASF - The Chemical Company

Pest Control Solutions

From: "Kumar, Rita" <Kumar.Rita@epa.gov>
To: Dana M Thomas <dana.thomas@basf.com>
Cc: "Hebert, John" <Hebert.John@epa.gov>
Date: 06/28/2013 03:15 PM
Subject: New product application 499-LAI

Dana: I am doing preliminary review of this application, and have the following comments:

1. The letter of authorization from Mitsui is missing, for use of their generic data.
2. The basic CSF indicates there are two pages, but there is only 1 page in the submission. Please confirm how many pages the basic CSF is supposed to be.
3. Provide MRID number of the efficacy study that is done on a slightly different formulation.
4. I am puzzled why you provided the MSDS for the technical and other inerts. Can you pl explain? Thanks.

Regards,
Rita

499-LAI

Memorandum

Date: 06/24/13

To: PM 07, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:
- [X] fully accepted submission
- [ ] partially accepted submission
- [ ] rejected submission

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 21, 2013

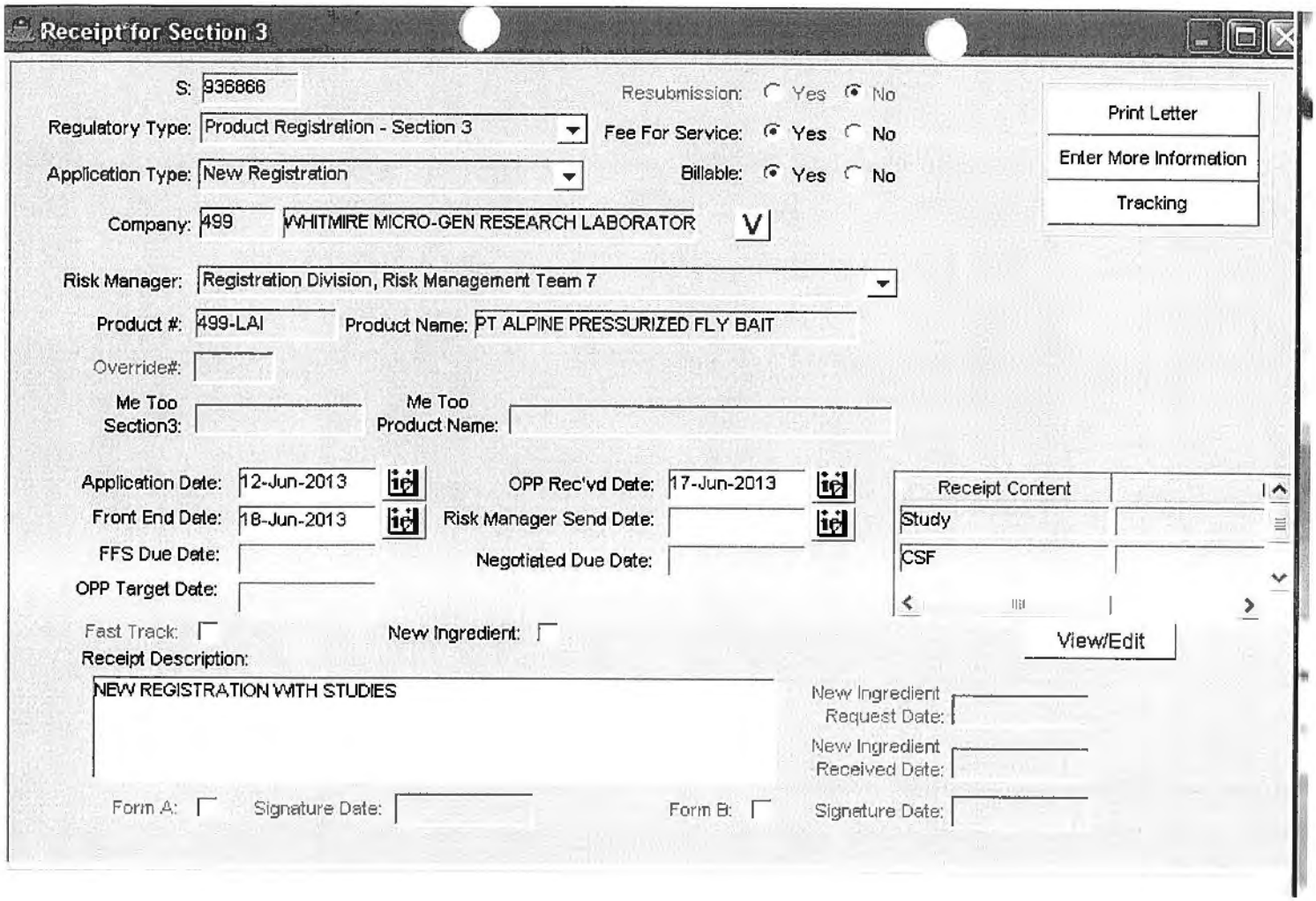
OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

BASF CORPORATION
WHITMIRE MICRO-GEN RESEARCH LABORATORIES, INC.
3568 TREE COURT INDUSTRIAL BLVD.
ST. LOUIS, MO 63122-6682

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 17-JUN-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.


Receipt for Section 3
S: 936866
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 499 WHITMIRE MICRO-GEN RESEARCH LABORATOR
Risk Manager: Registration Division, Risk Management Team 7
Product #: 499-LAI
Product Name: PT ALPINE PRESSURIZED FLY BAIT
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 12-Jun-2013
OPP Rec'vd Date: 17-Jun-2013
Front End Date: 18-Jun-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
NEW REGISTRATION WITH STUDIES
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

BASF
The Chemical Company

June 12, 2013

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Document Processing Desk (REGFEE)
OPP/IB/RD (7504P)
U.S. Environmental Protection Agency
ATTN: Mr. John Hebert, PM 7
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Re: **Application for Registration**
PT® Alpine® Pressurized Fly Bait, EPA Reg. No. 499-xxx
PRIA Proposed Category/Fee: R310, $4,807.00 [7 mo review]

Dear Mr. Hebert:

Enclosed, in support of the referenced application, is the following documentation:

- Transmittal Document (with associated data)
- Application for Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Copy of Check #01872056 in the amount of $4,807.00
- Certification Statement in Compliance with 40 CFR 158.350
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statements of Formula (CSFs); Basic & Alternate 1
- Confidential copy of two earlier formulations (395 KA I, FC 237-093 and BAS 395 KB I, FC 237-094) that are not being registered, but were used to conduct one of the submitted efficacy studies
- A safety data sheet for each ingredient in the formulation
- Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-37)
- Summary of the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-36)
- Data Matrix (EPA Form 8570-35)
  - ✓ Agency Internal Use Copy
  - ✓ Public File Copy
- Label Certification Statement
- Draft labeling (5 hard copies, and one 'pdf' electronic file)

This EP is a RTU pressurized fly bait in an aerosol can. It contains 1.0% dinotefuran and is intended for use by pest management professionals. The product name on the application is PT® Alpine® Pressurized Fly Bait, which is the planned marketplace brand name. In the studies submitted for review, the product is identified by its project development tracking code, TC-333, and experimental formulation numbers, BAS 395 KC I and BAS 395 KE I. We now have a final formulation number for BAS 395 KE I, which is BAS 395 14 I. You might also see references to formula codes, FC 237-100 = BAS 395 KC I and FC 243-006 = BAS 395 KE I = BAS 395 14 I. All of these identify the test substances. BAS 395 KC I is represented by the Basic CSF, whereas BAS 395 14 I is represented by the CSF identified as Alternate 1.

BASF Corporation
Pest Control Solutions
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122

BASF
The Chemical Company

Product chemistry, acute toxicity and two of the four submitted efficacy studies were conducted using FC 237-100/BAS 395 KC I (Basic CSF). Also submitted is an efficacy study using both FC 237-100/BAS 395 KC I (Basic CSF) and FC 243-005/BAS 395 KE I/BAS 395 14 I (Alternate 1 CSF) to bridge the data, showing no change in efficacy. The only difference between the two formulations is [redacted] One of the submitted efficacy studies was conducted on two earlier formulations that we are not registering, but I have enclosed a copy of the respective confidential formula sheets for reference. Both formulations vary little from the two formulations we are registering. Both BAS 395 KA I and BAS 395 KB I contain [redacted]

With regard to the CSFs, we are requesting non-standard upper and lower certified limits for the [redacted]

Thank you for your assistance in the review and approval process. Please don't hesitate to contact me at (636) 861-4223 or via electronic mail at dana.thomas@basf.com, should you have any questions or need additional information.

Sincerely,

Dana M. Thomas
Product Regulatory Manager
Authorized Agent for Whitmire Micro-Gen Research Laboratories, Inc.

Encl.

TRANSMITTAL DOCUMENT

Applicant:
Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122-6682

Submitter: Dana Thomas
Email: dana.thomas@basf.com
Telephone: (636) 861-4223

Reason for Transmittal:
Application for Registration: PT® Alpine® Pressurized Fly Bait
PRIA Proposed Category/Fee: R310; $4,807.00
EPA File Symbol 499-xxx

Date of Transmittal: June 12, 2013

Administrative Material Included in Submission:

1. Cover letter, dated June 12, 2013
2. Application (Form 8570-1)
3. Certification with Respect to Citation of Data (Form 8570-34)
4. Copy of Check #01872056 in the amount of $4,807.00
5. Certification Statement in Compliance with 40 CFR 158.350
6. Formulators Exemption (Form 8570-27)
7. Confidential Statements of Formula (CSF(s), dated June 12, 2013
   - ✓ Basic
   - ✓ Alternate 1
8. Confidential Copy of two earlier formulations (BAS 395 KA I, FC 237-093 and BAS 395 KB I, FC 237-094) that are not being registered, but were used to conduct one of the submitted efficacy studies.
9. A safety data sheet for each ingredient in the formulation(s)
10. Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-37)
11. Summary of the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-36)
12. Data Matrix (Form 8570-35)
    - ✓ Agency Internal Use Copy
    - ✓ Public File Copy
13. Label Certification Statement
14. Five (5) copies draft labeling

Studies Included in Submission:

Product Chemistry *(3 bound copies)*

- Product Chemistry Part A Data Requirements and Part B Results Summary for Study No. 12-0653 for PT® Alpine® Pressurized Fly Bait (aka TC-333); BASF Corporation, Pest Control Solutions / Whitmire Micro-Gen Research Laboratories, Inc.

MRID No. **49155101**

114

Acute Toxicity *(3 bound copies)*

- Acute Oral Toxicity Up and Down Procedure in Rats; Product Safety Labs, Laboratory Study No. 35511

MRID No. **49155102**

- Acute Dermal Toxicity Study in Rats; Product Safety Labs, Laboratory Study No. 35512

MRID No. **49155103**

- Acute Inhalation Toxicity Study in Rats – Limit Test; Product Safety Labs, Laboratory Study No. 35513

MRID No. **49155104**

- Primary Eye Irritation Study in Rabbits; Product Safety Labs, Laboratory Study No. 35514

MRID No. **49155105**

- Primary Skin Irritation Study in Rabbits; Product Safety Labs, Laboratory Study No. 35515

MRID No. **49155106**

- Dermal Sensitization Study in Guinea Pigs (Buehler Method); Product Safety Labs, Laboratory Study No. 35516

MRID No. **49155107**

Product Performance/Efficacy *(3 bound copies)*

- Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions; Sierra Research Laboratories, Inc., Laboratory Project ID: #BAS12-1-SS / BASF DIMeS #2005 / RAS #3397

MRID No. **49155108**

- Efficacy of TC-333 Aerosol Fly Bait (1.0% Dinotefuran) against House Flies (*Musca domestica*); Snell Scientifics, LLC, Laboratory Project ID: DIMeS #2080 / RAS #3394

MRID No. **49155109**

- Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica,* on Animal Confinement Facilities in Central California; Sierra Research Laboratories, Inc., Laboratory Project ID: BAS12-12A-DN / BASF DIMeS #2044 / RAS #3378

  MRID No. **49155110**

- Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*); Snell Scientifics, LLC, Laboratory Project ID: DIMeS #2053 / RAS #3355

  MRID No. **49155111**

Name: Dana M. Thomas **Signature:** Dana M Thomas

Title: Product Regulatory Mgr. **Date:** June 12, 2013

21-Day Screen Completed by Contractor

21-Day Expires on 7-8-13

Jacket # 499-LAI
MRID# 491551

Content Screen: Recommend to Pass/Fail

11-3 Review: Pass/Fail/NA

Overall Status: Recommend to Pass/Fail

Transfer This Jacket to:

STEPHEN SCHAIBLE

07

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 6/17/13

Experts In-Processing Signature: MB Date 6/18/13 Fee Paid: Yes ✓

Division management contacted on issues No ____ Yes ____ Date ____

EPA Reg. Number: 499-LAE	EPA Receipt Date: 6/17/13

	Items for Review	Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type	X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)	X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A) — yes: X / no:			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)	X		
	Certificate and data matrix consistent	X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B) — yes: / no:			
	If applicable, is there a letter of Authorization for exclusive use only.			
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)	X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)	X		
	a) Selective Method (Fee category experts use) — yes: X / no:			
	b) Cite-All (Fee category experts use)			
	c) Applicant owns all data (Fee category experts use)			
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**	X		
7	**Is the data package consistent with PR Notice 86-5**	X		
8	**Notice of Filing included with petitions**			X

9	**If applicable for conventional applications, <u>reduced risk rationale</u>**			✓
10	**<u>Required Data</u> and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* Inerts approved for non-food use

Jacket Pass
§11-03 Pass

TRID 491551

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

R 310

New products must either: 1) supply the product specific acute toxicity 6 pack data (listed below), or 2) provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Data submitted		Cited	
		Yes	No	Yes	No
870.1100	Acute Oral (LD50)	X			
870.1200	Acute Dermal (LD50)	X			
870.1300	Acute Inhalation (LC50)	X			
870.2400	Acute Eye Irritation	X			
870.2500	Acute Dermal Irritation	X			
870.2600	Dermal Sensitization	X			

Efficacy – which guideline is used depends on the proposed label use

Guideline No.	Study Title	Data submitted		Cited		Comments
		Yes	No	Yes	No	
810.3100	Soil Treatments for Imported Fire Ants					
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments					
810.3300	Treatments to Control Pests of Humans and Pets					
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments					
810.3500	Premises Treatments					
810.3600	Structural Treatments					
810.3800	Methods for Efficacy Testing of Termite Baits					

R 310

End Use (EP) or Manufacturing Use (MP) product or Technical Grade of the Active Ingredient (TGAI). Must submit Group A and B product chemistry data for each proposed product unless it's a 100% identical (repack): YES or (NO) (circle one)

Guideline No.	Group A: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.1550	Product Identity & Composition	X					
830.1600	Description of materials used to produce the product	X					
830.1650	Description of formulation process	X					
830.1670	Discussion on the formation of impurities	X					
830.1700	Preliminary analysis	X					
830.1750	Certified limits (158.345)	X					
830.1800	Enforcement analytical method	X					

Guideline No.	Group B: Product Chemistry Data Study Title	EP Data Submitted		MP Data Submitted		TGAI	
		Yes	No	Yes	No	Yes	No
830.6302	Color	X					
830.6303	Physical State	X					
830.6304	Odor	X					
830.6313	Stability to normal and elevated temperatures metal and metal ions						
830.6314	Oxidation/Reduction (Chemical incompatibility)	X					
830.6315	Flammability	X					
830.6316	Explodability	X					
830.6317	Storage stability	X					
830.6319	Miscibility	X					
830.6320	Corrosion Characteristics	X					
830.6321	Dielectric Breakdown Voltage	X					
830.7000	pH	X					
830.7050	UV/ Visible Absorption						
830.7100	Viscosity	X					
830.7200	Melting Point						
830.7220	Boiling Point						
830.7300	Density	X					
830.7370	Dissociation Constant						
830.7550	Partition Coefficient						
830.7840	Water Solubility						
830.7950	Vapor Pressure						

Grayed out = data not required

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

June 19, 2013

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-480032
EPA File Symbol or Registration Number: 499-LAI
Product Name: PT ALPINE PRESSURIZED FLY BAIT
EPA Receipt Date: 17-Jun-2013
EPA Company Number: 499
Company Name: WHITMIRE MICRO-GEN RESEARCH LABORATORIES, INC.

MS. DANA THOMAS
BASF CORPORATION
WHITMIRE MICRO-GEN RESEARCH LABORATORIES, INC.
3568 TREE COURT INDUSTRIAL BLVD.
ST. LOUIS, MO 63122-6682

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code R310:
NEW END-USE OR MANUFACTURING USE PRODUCT WITH REGISTERED SOURCE(S) OF ACTIVE INGREDIENT(S);INCLUDES PRODUCTS CONTAINING TWO OR MORE REGISTERED ACTIVE INGREDIENTS PREVIOUSLY COMBINED IN OTHER REGISTERED PRODUCTS;REQUIRES REVIEW OF DATA PACKAGE WITHIN RD ONLY;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);CHILD RESISTANT PACKAGING;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service {936866W~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 7

Receipt No. S-	936866
EPA File Symbol/Reg. No.	499-LAI
Pin-Punch Date:	6/17/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R-330

Granted: R-330

Amount Due: $ 4807.00

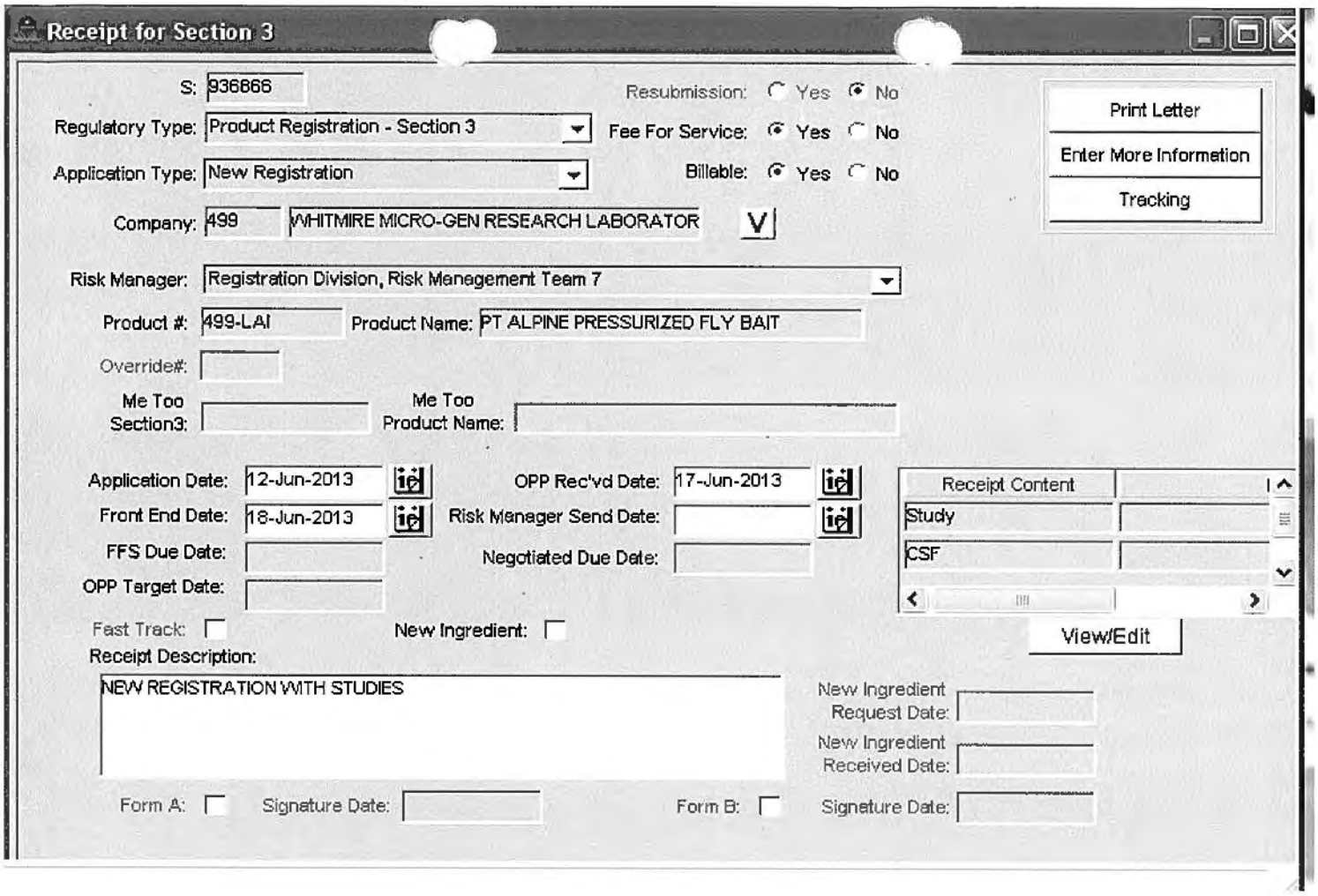
Parent/Child Decisions:

☐ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Venus Eagle Date: 7/19/13

Remarks:

Missing Formulators exemption form even though registrant states it was included?


Receipt for Section 3
S: 936866
Resubmission: Yes No
Regulatory Type: Product Registration - Section 3
Fee For Service: Yes No
Application Type: New Registration
Billable: Yes No
Print Letter
Enter More Information
Tracking
Company: 499 WHITMIRE MICRO-GEN RESEARCH LABORATOR
Risk Manager: Registration Division, Risk Management Team 7
Product #: 499-LAI
Product Name: PT ALPINE PRESSURIZED FLY BAIT
Override#:
Me Too Section3:
Me Too Product Name:
Application Date: 12-Jun-2013
OPP Rec'vd Date: 17-Jun-2013
Front End Date: 18-Jun-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
Receipt Content
Study
CSF
Fast Track:
New Ingredient:
View/Edit
Receipt Description:
NEW REGISTRATION WITH STUDIES
New Ingredient Request Date:
New Ingredient Received Date:
Form A:
Signature Date:
Form B:
Signature Date:

01872056

DOCUMENT NO	INV DATE	INVOICE NO	GROSS AMOUNT	DISCOUNT AMOUNT	NET AMOUNT
12193629	05/07/2013	TC-333	4,807.00	0.00	4,807.00
			4,807.00	0.00	4,807.00

Date 05/08/2013

Direct Payment Inquiries to (973) 245-5530

Your Account with us 1787917
Payment Document 1080811966
AP_INQUIRY_MAIL_BOX@BASF.COM
Hold Code 56 D. M. THOMAS 476-4223

Payment Amount
*********4,807.00* USD

BASF Corporation
100 Park Ave
Florham Park, NJ 07932-0685

REMOVE DOCUMENT ALONG THIS PERFORATION

THIS DOCUMENT IS PRINTED IN TWO COLORS. DO NOT ACCEPT UNLESS BLUE AND BURGUNDY ARE PRESENT.

BASF Corporation
100 Park Ave
Florham Park, NJ 07932-0685

62-38
311

No. 01872056

DATE
05 08 2013

*** FOUR THOUSAND EIGHT HUNDRED SEVEN USD*** *********4,807.00* USD

U S ENVIRONMENTAL PROTECTION AGENCY
FIFRA SERVICE FEES
PO Box 979074
SAINT LOUIS MO 63197-9000

Deutsche Bank Trust Company Delaware
WILMINGTON

VOID AFTER 90 DAYS

⑈01872056⑈ ⑆031100380⑆ [redacted]

BASF Corporation
100 Park Ave
Florham Park, NJ 07932-0685

U S ENVIRONMENTAL PROTECTION AGENCY
FIFRA SERVICE FEES
PO Box 979074
SAINT LOUIS MO 63197-9000

128

Commercial/financial information may be entitled to confidential treatment

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060

United States
Environmental Protection Agency
Washington, DC 20460

[xxx] **Registration**
[ ] **Amendment**
[ ] **Other**

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
499-xxx	John Hebert	[xx] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
PT® Alpine® Pressurized Fly Bait	Team 7	

5. Name and Address of Applicant *(Include ZIP Code)*

Whitmire Micro-Gen Research Laboratories Inc.
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122-6682

[ ] *Check if this is a new address*

6. Expedited Reveiw. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in repsonse to Agency letter dated _____
[ ] "Me Too" Application.
[xx] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application for registration of a new end-use product. Proposed PRIA category: R310, $4,807.00. Please see cover letter for details.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes [xx] No	[ ] Yes [xx] No	[ ] Yes [xx] No	[xxxxx] Metal [ ] Plastic [ ] Glass [ ] Paper [ ] Other (Specify)
** Certification must be submitted*	If "Yes" Unit Packaging wgt. / No. per container	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	Range: 16 - 20 oz	[ ] Container label

6. Manner in Which Label is Affixed to Product [xxxxx] Lithograph [ ] Paper glued [ ] Stenciled [ ] Other _____

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
Dana Thomas	Product Regulatory Mgr.	636-861-4223

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title
Dana M Thomas	Product Regulatory Mgr.
4. Typed Name	**5. Date**
Dana M. Thomas	June 12, 2013

Form Approved. OMB No. 2070-0[illegible]070-0057, 2070-0107, 2070-0122, 2070-0164.

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
Whitmire Micro-Gen Research Laboratories, Inc. **3568 Tree Court Industrial Boulevard** **St. Louis, MO 63122**	499-xxx Product Name **PT® Alpine® Pressurized Fly Bait** Date of Confidential Statement of Formula (EPA Form 8570-4) **June 12, 2013**

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):
Dinotefuran, CAS #165252-70-0

(2)

Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person, and meets the requirements of 40 CFR Section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

[X] (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

[ ] (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, and accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption

Active Ingredient	Source: Product Name	Source: Registration Number
Dinotefuran	[redacted]	[redacted]

Signature	Name and Title	Date
Dana M. Thomas	Dana M. Thomas Manager, Product Registrations	6/12/2013

EPA Form 8570-27(Rev. 06-2004)

Copy 1 - EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

BASF
The Chemical Company

June 12, 2013

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Document Processing Desk (REGFEE)
OPP/IB/RD (7504P)
U.S. Environmental Protection Agency
ATTN: Mr. John Hebert, PM 7
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Re: Application for Registration
PT® Alpine® Pressurized Fly Bait, EPA Reg. No. 499-xxx
PRIA Proposed Category/Fee: R310, $4,807.00 [7 mo review]

Dear Mr. Hebert:

Enclosed, in support of the referenced application, is the following documentation:

- Transmittal Document (with associated data)
- Application for Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Copy of Check #01872056 in the amount of $4,807.00
- Certification Statement in Compliance with 40 CFR 158.350
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statements of Formula (CSFs); Basic & Alternate 1
- Confidential copy of two earlier formulations (395 KA I, FC 237-093 and BAS 395 KB I, FC 237-094) that are not being registered, but were used to conduct one of the submitted efficacy studies
- A safety data sheet for each ingredient in the formulation
- Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-37)
- Summary of the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-36)
- Data Matrix (EPA Form 8570-35)
  - ✓ Agency Internal Use Copy
  - ✓ Public File Copy
- Label Certification Statement
- Draft labeling (5 hard copies, and one 'pdf' electronic file)

This EP is a RTU pressurized fly bait in an aerosol can. It contains 1.0% dinotefuran and is intended for use by pest management professionals. The product name on the application is PT® Alpine® Pressurized Fly Bait, which is the planned marketplace brand name. In the studies submitted for review, the product is identified by its project development tracking code, TC-333, and experimental formulation numbers, BAS 395 KC I and BAS 395 KE I. We now have a final formulation number for BAS 395 KE I, which is BAS 395 14 I. You might also see references to formula codes, FC 237-100 = BAS 395 KC I and FC 243-006 = BAS 395 KE I = BAS 395 14 I. All of these identify the test substances. BAS 395 KC I is represented by the Basic CSF, whereas BAS 395 14 I is represented by the CSF identified as Alternate 1.

BASF Corporation
Pest Control Solutions
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122

BASF
The Chemical Company

Product chemistry, acute toxicity and two of the four submitted efficacy studies were conducted using FC 237-100/BAS 395 KC I (Basic CSF). Also submitted is an efficacy study using both FC 237-100/BAS 395 KC I (Basic CSF) and FC 243-006/BAS 395 KE I/BAS 395 14 I (Alternate 1 CSF) to bridge the data, showing no change in efficacy. The only difference between the two formulations is [redacted] One of the submitted efficacy studies was conducted on two earlier formulations that we are not registering, but I have enclosed a copy of the respective confidential formula sheets for reference. Both formulations vary little from the two formulations we are registering. Both BAS 395 KA I and BAS 395 KB I contain [redacted]

With regard to the CSFs, we are requesting non-standard upper and lower certified limits for the [redacted]

Thank you for your assistance in the review and approval process. Please don't hesitate to contact me at (636) 861-4223 or via electronic mail at dana.thomas@basf.com, should you have any questions or need additional information.

Sincerely,

Dana M. Thomas
Product Regulatory Manager
Authorized Agent for Whitmire Micro-Gen Research Laboratories, Inc.

Encl.

TRANSMITTAL DOCUMENT

Applicant:
Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122-6682
Submitter: Dana Thomas
Email: dana.thomas@basf.com
Telephone: (636) 861-4223

Reason for Transmittal:
Application for Registration: PT® Alpine® Pressurized Fly Bait
PRIA Proposed Category/Fee: R310; $4,807.00
EPA File Symbol 499-xxx

Date of Transmittal: June 12, 2013

Administrative Material Included in Submission:

1. Cover letter, dated June 12, 2013
2. Application (Form 8570-1)
3. Certification with Respect to Citation of Data (Form 8570-34)
4. Copy of Check #01872056 in the amount of $4,807.00
5. Certification Statement in Compliance with 40 CFR 158.350
6. Formulators Exemption (Form 8570-27)
7. Confidential Statements of Formula (CSF(s), dated June 12, 2013
   - ✓ Basic
   - ✓ Alternate 1
8. Confidential Copy of two earlier formulations (BAS 395 KA I, FC 237-093 and BAS 395 KB I, FC 237-094) that are not being registered, but were used to conduct one of the submitted efficacy studies.
9. A safety data sheet for each ingredient in the formulation(s)
10. Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-37)
11. Summary of the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-36)
12. Data Matrix (Form 8570-35)
    - ✓ Agency Internal Use Copy
    - ✓ Public File Copy
13. Label Certification Statement
14. Five (5) copies draft labeling

Studies Included in Submission:

Product Chemistry *(3 bound copies)*

- Product Chemistry Part A Data Requirements and Part B Results Summary for Study No. 12-0653 for PT® Alpine® Pressurized Fly Bait (aka TC-333); BASF Corporation, Pest Control Solutions / Whitmire Micro-Gen Research Laboratories, Inc.

MRID No. _____

Acute Toxicity *(3 bound copies)*

- Acute Oral Toxicity Up and Down Procedure in Rats; Product Safety Labs, Laboratory Study No. 35511

MRID No. _____

- Acute Dermal Toxicity Study in Rats; Product Safety Labs, Laboratory Study No. 35512

MRID No. _____

- Acute Inhalation Toxicity Study in Rats – Limit Test; Product Safety Labs, Laboratory Study No. 35513

MRID No. _____

- Primary Eye Irritation Study in Rabbits; Product Safety Labs, Laboratory Study No. 35514

MRID No. _____

- Primary Skin Irritation Study in Rabbits; Product Safety Labs, Laboratory Study No. 35515

MRID No. _____

- Dermal Sensitization Study in Guinea Pigs (Buehler Method); Product Safety Labs, Laboratory Study No. 35516

MRID No. _____

Product Performance/Efficacy *(3 bound copies)*

- Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions; Sierra Research Laboratories, Inc., Laboratory Project ID: #BAS12-1-SS / BASF DIMeS #2005 / RAS #3397

MRID No. _____

- Efficacy of TC-333 Aerosol Fly Bait (1.0% Dinotefuran) against House Flies (*Musca domestica*); Snell Scientifics, LLC, Laboratory Project ID: DIMeS #2080 / RAS #3394

MRID No. _____

- Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica,* on Animal Confinement Facilities in Central California; Sierra Research Laboratories, Inc., Laboratory Project ID: BAS12-12A-DN / BASF DIMeS #2044 / RAS #3378

  MRID No. _____

- Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*); Snell Scientifics, LLC, Laboratory Project ID: DIMeS #2053 / RAS #3355

  MRID No. _____

Name: Dana M. Thomas **Signature:** Dana M Thomas

Title: Product Regulatory Mgr. **Date:** June 12, 2013

Form Approved. OMB Nos. 2070-0060; 2070-0057; 2070-0107

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

SELF-CERTIFICATION STATEMENT FOR THE PHYSICAL/CHEMICAL PROPERTIES (PR NOTICE 98-1)

Product Name: PT® Alpine® Pressurized Fly Bait

Reg. No./File Symbol No.
(if known) or Company No. 499-xxx

SELF-CERTIFICATION STATEMENT:

I certify that the reported information on the "Summary Form" represents a true and accurate record of the test results of studies generated or owned by (Company Name): BASF Corporation (on behalf of Whitmire Micro-Gen Research Labs, Inc.) and that the values of the properties reported are reliable. I further certify that such data were generated in substantial conformity with OPPTS Test Guideline Series 830 Product Properties, applicable to my product, and in effect at the time of submission.

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of section 12(a)(2)(N) of FIFRA without opportunity for hearing, if I have not submitted to EPA within thirty (30) days of receipt of a request by the Agency, or within a specified time agreed to by the Agency, test results of studies summarized in the "Summary Form."

As a condition of registration, EPA may, by order, (1) withdraw a pending registration, (2) suspend the registration of this product without opportunity for hearing, or (3) assess civil penalties provided for in section 14 of FIFRA for violations of sections 12(a)(2)(N), 12(a)(2)(Q), or 12(a)(2)(R) of FIFRA without opportunity for hearing, if I fail to provide to EPA within thirty (30) days of receipt of a notification of error, or within a specified time agreed to by the Agency, information that EPA determines is required to correct the error.

Type Applicant's Name: Dana M. Thomas

Title: Product Regulatory Mgr.	Telephone No. 636-861-4223
Applicant's Signature: Dana M Thomas	Date: June 12, 2013

EPA Form 8570-37 (12-2003)

Attach-2

Print Form

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1 hour per response for registration activities and 1 hour per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Mangaement Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

SUMMARY OF THE PHYSICAL/CHEMICAL PROPERTIES (PR Notice 98-1)

1. PRODUCT NAME: PT® Alpine® Pressurized Fly Bait		**2. Reg. No.** 499-xxx
3. COMPANY NAME: Whitmire Micro-Gen Research Laboratories, Inc.		**4. SUBMISSION DATE:** June 12, 2013
5. FIRST SUBMISSION ☒ **6. RESUBMISSION** ☐	**7. PESTICIDE TYPE:** Insecticide	**10. REGISTRATION** [☒
8. FORMULATED MANUFACTURING-USE PRODUCT ☐ **or 9. END-USE PRODUCT** ☒		**11. REREGISTRATION** [☐
13. PRODUCT MANAGER OR CHEMICAL REVIEW MANAGER #/NAME (IF KNOWN): John Hebert, PM 7		**12. REREG CASE #**

14. GUIDELINE REFERENCE NO.(GRN)/TITLE		15. VALUE or QUALITATIVE DESCRIPTION/METHOD(s) USED WHERE APPLICABLE AND REFERENCES	16. MRID or REPORT NO.
Group B, Series 830-Physical and Chemical Properties (40 CFR 158.190)			
-6302	Color	NA - "end use" product / pale yellow	12-0653
-6303	Physical State	Liquid	12-0653
-6304	Odor	NA - "end use" product / characteristic of acetone	12-0653
-6314	Oxidation/Reduction: Chemical Incompatibility	NA - product does not contain any oxidizing or reducing agents.	
-6315	Flammability/Flame Extension	Flame extension = 7"; no flashback	12-0653
-6316	Explodability	NA - product does not contain an explosive agent.	
-6317	Storage Stability	In Progress	12-0652
-6319	Miscibility	NA - product is not an emulsifiable liquid intended to be diluted with petroleum distillate.	
-6320	Corrosion Characteristics	In Progress	12-0652
-6321	Dielectric Breakdown Voltage	NA - product is not intended to be used around electrical equipment.	
-7000	pH	8.940 @ 24.4°C	12-0653
-7100	Viscosity	2.34 cps @ 20.0°C	12-0653
-7300	Density/Relative Density/ Bulk Density	8.35 lbs/gal (1.0000 g/ml) @ 20.0°C	12-0653

EPA Form 8570-36 (07/JAN/1998)

BASF
The Chemical Company

June 12, 2013

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

Document Processing Desk (REGFEE)
OPP/IB/RD (7504P)
U.S. Environmental Protection Agency
ATTN: Mr. John Hebert, PM 7
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Re: Application for Registration
PT® Alpine® Pressurized Fly Bait, EPA Reg. No. 499-xxx
PRIA Proposed Category/Fee: R310, $4,807.00 [7 mo review]

Dear Mr. Hebert:

Enclosed, in support of the referenced application, is the following documentation:

- Transmittal Document (with associated data)
- Application for Registration (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Copy of Check #01872056 in the amount of $4,807.00
- Certification Statement in Compliance with 40 CFR 158.350
- Formulator's Exemption Statement (EPA Form 8570-27)
- Confidential Statements of Formula (CSFs); Basic & Alternate 1
- Confidential copy of two earlier formulations (395 KA I, FC 237-093 and BAS 395 KB I, FC 237-094) that are not being registered, but were used to conduct one of the submitted efficacy studies
- A safety data sheet for each ingredient in the formulation
- Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-37)
- Summary of the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-36)
- Data Matrix (EPA Form 8570-35)
  - ✓ Agency Internal Use Copy
  - ✓ Public File Copy
- Label Certification Statement
- Draft labeling (5 hard copies, and one 'pdf' electronic file)

This EP is a RTU pressurized fly bait in an aerosol can. It contains 1.0% dinotefuran and is intended for use by pest management professionals. The product name on the application is PT® Alpine® Pressurized Fly Bait, which is the planned marketplace brand name. In the studies submitted for review, the product is identified by its project development tracking code, TC-333, and experimental formulation numbers, BAS 395 KC I and BAS 395 KE I. We now have a final formulation number for BAS 395 KE I, which is BAS 395 14 I. You might also see references to formula codes, FC 237-100 = BAS 395 KC I and FC 243-006 = BAS 395 KE I = BAS 395 14 I. All of these identify the test substances. BAS 395 KC I is represented by the Basic CSF, whereas BAS 395 14 I is represented by the CSF identified as Alternate 1.

BASF Corporation
Pest Control Solutions
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122

BASF
The Chemical Company

Product chemistry, acute toxicity and two of the four submitted efficacy studies were conducted using FC 237-100/BAS 395 KC I (Basic CSF). Also submitted is an efficacy study using both FC 237-100/BAS 395 KC I (Basic CSF) and FC 242-005/BAS 395 KE I/BAS 395 14 I (Alternate 1 CSF) to bridge the data, showing no change in efficacy. The only difference between the two formulations is [redacted] One of the submitted efficacy studies was conducted on two earlier formulations that we are not registering, but I have enclosed a copy of the respective confidential formula sheets for reference. Both formulations vary little from the two formulations we are registering. Both BAS 395 KA I and BAS 395 KB I contain [redacted]

With regard to the CSFs, we are requesting non-standard upper and lower certified limits for the [redacted]

Thank you for your assistance in the review and approval process. Please don't hesitate to contact me at (636) 861-4223 or via electronic mail at dana.thomas@basf.com, should you have any questions or need additional information.

Sincerely,

Dana M. Thomas
Product Regulatory Manager
Authorized Agent for Whitmire Micro-Gen Research Laboratories, Inc.

Encl.

TRANSMITTAL DOCUMENT

Applicant:
Whitmire Micro-Gen Research Laboratories, Inc.
3568 Tree Court Industrial Blvd.
St. Louis, MO 63122-6682
Submitter: Dana Thomas
Email: dana.thomas@basf.com
Telephone: (636) 861-4223

Reason for Transmittal:
Application for Registration: PT® Alpine® Pressurized Fly Bait
PRIA Proposed Category/Fee: R310; $4,807.00
EPA File Symbol 499-xxx

Date of Transmittal: June 12, 2013

Administrative Material Included in Submission:

1. Cover letter, dated June 12, 2013
2. Application (Form 8570-1)
3. Certification with Respect to Citation of Data (Form 8570-34)
4. Copy of Check #01872056 in the amount of $4,807.00
5. Certification Statement in Compliance with 40 CFR 158.350
6. Formulators Exemption (Form 8570-27)
7. Confidential Statements of Formula (CSF(s), dated June 12, 2013
   - ✓ Basic
   - ✓ Alternate 1
8. Confidential Copy of two earlier formulations (BAS 395 KA I, FC 237-093 and BAS 395 KB I, FC 237-094) that are not being registered, but were used to conduct one of the submitted efficacy studies.
9. A safety data sheet for each ingredient in the formulation(s)
10. Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-37)
11. Summary of the Physical/Chemical Properties (PR Notice 98-1) (Form 8570-36)
12. Data Matrix (Form 8570-35)
    - ✓ Agency Internal Use Copy
    - ✓ Public File Copy
13. Label Certification Statement
14. Five (5) copies draft labeling

Studies Included in Submission:

Product Chemistry *(3 bound copies)*

- Product Chemistry Part A Data Requirements and Part B Results Summary for Study No. 12-0653 for PT® Alpine® Pressurized Fly Bait (aka TC-333); BASF Corporation, Pest Control Solutions / Whitmire Micro-Gen Research Laboratories, Inc.

MRID No. **49155101**

Acute Toxicity *(3 bound copies)*

- Acute Oral Toxicity Up and Down Procedure in Rats; Product Safety Labs, Laboratory Study No. 35511

MRID No. **49155102**

- Acute Dermal Toxicity Study in Rats; Product Safety Labs, Laboratory Study No. 35512

MRID No. **49155103**

- Acute Inhalation Toxicity Study in Rats – Limit Test; Product Safety Labs, Laboratory Study No. 35513

MRID No. **49155104**

- Primary Eye Irritation Study in Rabbits; Product Safety Labs, Laboratory Study No. 35514

MRID No. **49155105**

- Primary Skin Irritation Study in Rabbits; Product Safety Labs, Laboratory Study No. 35515

MRID No. **49155106**

- Dermal Sensitization Study in Guinea Pigs (Buehler Method); Product Safety Labs, Laboratory Study No. 35516

MRID No. **49155107**

Product Performance/Efficacy *(3 bound copies)*

- Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions; Sierra Research Laboratories, Inc., Laboratory Project ID: #BAS12-1-SS / BASF DIMeS #2005 / RAS #3397

MRID No. **49155108**

- Efficacy of TC-333 Aerosol Fly Bait (1.0% Dinotefuran) against House Flies (*Musca domestica*); Snell Scientifics, LLC, Laboratory Project ID: DIMeS #2080 / RAS #3394

MRID No. **49155109**

- Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica*, on Animal Confinement Facilities in Central California; Sierra Research Laboratories, Inc., Laboratory Project ID: BAS12-12A-DN / BASF DIMeS #2044 / RAS #3378

  MRID No. **49155110**

- Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*); Snell Scientifics, LLC, Laboratory Project ID: DIMeS #2053 / RAS #3355

  MRID No. **49155111**

Name: Dana M. Thomas **Signature:** Dana M Thomas

Title: Product Regulatory Mgr. **Date:** June 12, 2013

Pages 143-195 – *Inert ingredient and product ingredient source information may be entitled to confidential treatment*

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number 636-861-4223 Whitmire Micro-Gen Research Laboratories, Inc., 3568 Tree Ct. Ind. Blvd., St. Louis MO 63122-6682	EPA Registration Number/File Symbol 499-xxx
Active Ingredient(s) and/or representative test compound(s) Dinotefuran, CAS #165252-70-0	Date June 12, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Indoor, Domestic Outdoor	Product Name PT® Alpine® Pressurized Fly Bait

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
Dana M Thomas	6/12/13	Dana M. Thomas, Product Regulatory Mgr.

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

CERTIFICATION STATEMENT

In Compliance with 40 CFR 158.350

For:

PT® Alpine® Pressurized Fly Bait
EPA Reg. No. 499-xxx

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of PT® Alpine® Pressurized Fly Bait, EPA Reg. No. 499-xxx, refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

Signed: Dana M Thomas

Dana M. Thomas
Product Regulatory Mgr.

Dated: June 12, 2013

EPA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Paperwork Reduction Act Notice: The public reporting burden fer this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: June 12, 2013	EPA Reg. No./File Symbol: 499-xxx Page 1 of 3
Applicant's/Registrant's Name & Address Whitmire Micro-Gen Research Laboratories, Inc; 3568 Tree Court Industrial Blvd., St. Louis, MO 63122-6682	Product PT® Alpine® Pressurized Fly Bait

Ingredient: Dinotefuran, CAS #165252-70-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.300 - 158.355	PRODUCT CHEMISTRY				
830.1550	Product Identity		Applicant; 499	OWN	
830.1650	Manufacturing Process		Applicant; 499	OWN	
830.1670	Discussion of formation of impurities		Applicant; 499	OWN	
830.1700	Preliminary Analysis		Applicant; 499	OWN	
830.1750	Certificate of limits		Applicant; 499	OWN	
830.1800	Analytical Methods		Applicant; 499	OWN	
830.6302	Color		Applicant; 499	OWN	
830.6303	Physical State		Applicant; 499	OWN	
830.6304	Odor		Applicant; 499	OWN	
830.7200	Melting Point		Applicant; 499	OWN	
830.7220	Boiling Point		Applicant; 499	OWN	
830.7300	Density, bulk-density, or specific gravity		Applicant; 499	OWN	
830.7840 or 830.7860	Solubility		Applicant; 499	OWN	
830.7950	Vapor Pressure		Applicant; 499	OWN	

Signature: Dana M Thomas
Name and Title: Dana M. Thomas, Product Regulatory Mgr.
Date: 6/12/13

EPA Form 8750-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

DATA MATRIX

Date: June 12, 2013

EPA Reg. No./File Symbol: 499-xxx

Applicant's/Registrant's Name & Address

Whitmire Micro-Gen Research Laboratories, Inc; 3568 Tree Court Industrial Blvd., St. Louis, MO 63122-6682

Product

PT® Alpine® Pressurized Fly Bait

Ingredient: Dinotefuran, CAS #165252-70-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.300 - 158.355					
830.7370	Dissociation constant		Applicant; 499	OWN	
830.7550, 830.7560 or 830.7570	Octanol/water partition coefficient		Applicant; 499	OWN	
830.7000	pH		Applicant; 499	OWN	
830.6313	Stability		Applicant; 499	OWN	
830.6314	Oxidizing/Reducing reaction		Applicant; 499	OWN	
830.6315	Flammability		Applicant; 499	OWN	
830.6316	Explodability		Applicant; 499	OWN	
830.6317	Storage stability		Applicant; 499	OWN	
830.7100	Viscosity		Applicant; 499	OWN	
830.6319	Miscibility		Applicant; 499	OWN	
830.6320	Corrosion Characteristics		Applicant; 499	OWN	
830.6321	Dielectric breakdown voltage		Applicant; 499	OWN	

Signature: Dana M Thomas

Name and Title: Dana M. Thomas
Product Regulatory Mgr.

Date: 6/12/13

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: June 12, 2013	EPA Reg. No./File Symbol: 499-xxx Page 3 of 3
Applicant's/Registrant's Name & Address Whitmire Micro-Gen Research Laboratories, Inc; 3568 Tree Court Industrial Blvd., St. Louis, MO 63122-6682	Product PT® Alpine® Pressurized Fly Bait
Ingredient: Dinotefuran, CAS #165252-70-0	

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.500	Toxicology				
870.1100	Acute Oral LD-50, rat		Applicant; 499	OWN	
870.1200	Acute dermal LD-50		Applicant; 499	OWN	
870.1300	Acute inhalation LC-50, rat		Applicant; 499	OWN	
870.2400	Primary eye irritation, rabbit		Applicant; 499	OWN	
870.2500	Primary dermal irritation		Applicant; 499	OWN	
870.2600	Dermal sensitization		Applicant; 499	OWN	
158.400	Product Performance				
	Evaluations of Two Experimental Fly Bait Formulations (Aerosol/Liquid) Compared with an Industry Standard against Field Strain House Flies Under Laboratory Conditions		Applicant; 499	OWN	
	Efficacy of TC-333 Aerosol Fly Bait (1.0% Dinotefuran) against House Flies (*Musca domestica*)		Applicant; 499	OWN	
	Efficacy Evaluations of Two Aerosol/Liquid Fly Bait Formulations Against Endemic Populations of House Fly, *Musca domestica*, on Animal Confinement Facilities in Central California		Applicant; 499	OWN	
	Efficacy of TC-333 Aerosol Fly Bait (1.00% Dinotefuran) against House Flies (*Musca domestica*)		Applicant; 499	OWN	

Signature: Dana M Thomas

Name and Title: Dana M. Thomas
Product Regulatory Mgr.

Date:
6/12/13

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Ingredient: Dinotefuran, CAS #165252-70-0

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Applicant; 499	OWN	
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			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	

Signature: Dana M Thomas

Name and Title: Dana M. Thomas
Product Regulatory Mgr.

Date: 6/12/13

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
[redacted]					
			Applicant; 499	OWN	
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			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	

Signature: Dana M Thomas

Name and Title: Dana M. Thomas
Product Regulatory Mgr.

Date: 5/12/13

Form Approved OMB No. 2070-0060

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Date: June 12, 2013	EPA Reg. No./File Symbol: 499-xxx Page 3 of 3
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			Applicant; 499	OWN	
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			Applicant; 499	OWN	
			Applicant; 499	OWN	
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			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	
			Applicant; 499	OWN	

Signature: Dana M Thomas

Name and Title: Dana M. Thomas
Product Regulatory Mgr.

Date: 6/12/13

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL

EPA Registration #	Date Submitted to EPA	Electronic file name
499-xxx	June 12, 2013	000499-00xxx.20130515v10.PT Alpine Pressurized Fly Bait.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Dana M Thomas

Signature

6/12/13

Date

Dana M. Thomas

Name (typed)

Product Regulatory Mgr.

Title

PT® ALPINE®

Pressurized Fly Bait

KILLS: House Flies, Filth Flies, Lesser House Flies, Flesh Flies and Small Fruit or Vinegar Flies

FOR USE IN AND AROUND: Commercial, Residential, Industrial Buildings and Other Manmade Structures, Garbage or Refuse Bins and Receptacles, or other areas flies may be a nuisance or health hazard. [Apartments; Bakeries; Campgrounds; Carnivals; Circus; Concert Arenas; Condominiums; Confectionaries; County and State Fair Facilities; Dairy Areas; Farm Houses; Day Care Facilities; Festival Grounds, Food Handling Establishments; Food Processing Plants; Food Storage Areas; Food Vending Structures; Garages; Golf Courses; Grain Mills; Granaries; Homes; Hospitals; Hotels; Housing and Containment Areas (i.e., Arenas, Barns, Cages, Hatcheries, Houses, Hutches, Kennels, Parlors, Pens, Sheds, Shelters, Stables) for Animals (i.e., Avian, Bovine, Canine, Equine, Feline, Hircine, Leporine, Murine, Porcine); Interiorscapes; LEED Buildings (as specified below); Libraries; Marinas; Meat, Poultry & Egg Processing Facilities; Meat Packing Plants; Milk Rooms; Mobile Homes; Motor Homes; Motels; Museums; Nursing Homes; Outdoor Living Areas; Pavilions; Porches; Research Facilities; Resorts; Restaurants; Mobile Food Vendors; Parking Ramps; Poultry Facilities (including: Hatchery, Egg Packaging, Breeding Facilities); Public Picnic Areas; Public Restrooms; Recreational Rest Areas; Residential Backyards; Schools; Supermarkets; Tents or Temporary Shelters; Theme Parks; Terminals; Transportation Equipment (Buses, Barges, Boats, Ships, Trailers, Trains, Trucks); Utilities; Warehouses; Waysides; Wildlife Refuge Areas; Zoos]

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA Reg. No 499-xxx EPA Est. No. 7969-MO-1

Net Weight: _____

ACTIVE INGREDIENT:

Dinotefuran, N-methyl-N'-nitro-N-(tetrahydro-3-furanyl)methylguanidine	1.0%
OTHER INGREDIENTS:	99.0%
Total:	100.0%

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may also call 1-800-832-HELP (4357), 24 hr/day, 7/days/week.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to aquatic invertebrates. Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to aquatic organisms in water adjacent to treated areas.

This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area.

PHYSICAL OR CHEMICAL HAZARDS

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.

SMART SOLUTIONS FACTS	
A ready-to-use solution to kill flies in a broad range of urban environments. Provides attractancy properties which will aid in bringing flies into the treated bait area. Key attributes of this product include:	
PT® Alpine® Pressurized Fly Bait	▪ Quick Knockdown ▪ Proven attractancy for up to 30 days ▪ Kills flies for up to 30 days on non-porous surfaces. ▪ May be used in conjunction with a fly light program such as Vector Plasma®, Vector Plasma One® and Vector® Classic® for monitoring of results and fly population reduction. ▪ For best management practices, use the bait as part of an overall Integrated Pest Management (IPM) program utilizing residuals and contact sprays, traps and drain cleaners. For questions or comments, call 1-800-777-8570].

DIRECTIONS FOR USE

IT IS A VIOLATION OF FEDERAL LAW TO USE THIS PRODUCT IN A MANNER INCONSISTENT WITH ITS LABELING.

Read Entire Label. Use strictly in accordance with Precautionary Statements and Directions for Use, and with the applicable state and federal regulations. Apply bait only in areas that are out of reach of children and pets.

USE RESTRICTIONS

- Do not apply bait to surfaces which may reach excessive temperatures. Examples include portions of stoves, lighting above food preparation areas, ovens, grills, fume hoods, steam tables, toasters, fryers, dishwashers and hot water pipes.
- Do not apply directly on food preparation surfaces or dining surfaces where foods for consumption may come in contact.
- Do not apply bait in areas where animals can ingest product.
- Do not apply directly upon animals
- Do not apply to milking equipment in dairy areas
- Do not apply directly into any electronic equipment or areas where electrical short circuit could occur.
- Do not use in aircraft cabins; use in cargo areas only.

APPLICATION INSTRUCTIONS

AREA TREATMENT: Point can toward target area from a distance no further than 12 in (30 cm) and press down actuator. Make a light application at a rate of 2 In ft/sec and avoid run off or dripping from targeted area. Area treatments are effective where flies congregate, roost and feed which may include garbage receptacles and lids, refuge containers, under tables and benches, recycling bins, dumpsters, behind vending machines, plant/flower pots, under bars, calf hutch ceilings, eave areas, walls and/or areas where flies are likely to congregate or infest. Do not apply bait in areas that are frequently cleaned. This product will not adhere to surfaces that are dusty or greasy. Reapply when bait placements are no longer visible and/or reinfestation occurs. Use a water-dampened paper towel to remove unwanted bait placements and then discard in trash.

BAND TREATMENT: Spray from a distance no further away from targeted area than 6 in (15 cm) to create a band application at a rate of 2 In ft/sec. Band applications may be made to areas such as beam edges, receptacle edges, table or bench edges, around windows and window frames, under narrow eaves and other areas where there is a narrow area where flies land, roost and/or are likely to infest. Reapply when bait placements are no longer visible and /or reinfestation occurs. Use water-dampened paper towel to remove unwanted bait placements and then discard in trash.

REMOVABLE BAIT PLACEMENTS: Apply bait on a small object no larger than 24 in^2 and no smaller than 6 in^2 unless it is a rope or twine of at least 6 in long. Object may be made of wood, plastic, cardboard, index cards, nylon, metal or other suitable material such as insect light trap sticky boards. Place in areas of fly activity.

FOOD HANDLING ESTABLISHMENTS: Food/Feed handling establishments are places other than private residences in which food is held, processed, prepared or served, including those operating under the Federal meat, poultry, shell egg grading and egg products inspection programs.

Use within food preparation and food production areas of food handling establishments is limited to the interior of refuge receptacles, removable bait placements or in stations, such as installed fly light traps. For areas outside of the food preparation and food production rooms spot and/or band applications may be made to areas where flies congregate and rest.

Food/Feed Areas: Include areas for receiving, serving, storing (dry, cold, frozen, raw), packing (canning, bottling, wrapping, boxing), preparing (cleaning, slicing, cooking, grinding), edible waste storage and enclosed processing systems (mills, dairies, edible oils, syrups).

All removable bait placements must be clearly marked with the wording "Fly Bait, Do not touch" (written, typed or stickered on it) and must be secured to the surface with an adhesive material or tape. Placements should be recorded and inspected with each service to that area. Do not place removable bait placements over or on food preparation or food processing areas with the exception of baited sticky boards placed and secured inside fly light traps. The use of rope or twine is not allowed in food areas.

Non-Food/Feed Areas: Include areas such as garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, garages, mop closets and storage areas (after packaging, canning or bottling).

All removable bait placements must be clearly marked with the wording "Fly Bait, Do not touch". Place in areas conducive to fly activity, and out of reach of children and pets.

Rope & Twine: Hang in areas where flies roost and/or congregate. Place a sticker or label clearly marked with the wording "Fly Bait, Do not touch" (written or typed) at the bottom of the rope or twine. Place in areas out of reach of children, pets and livestock.

PREVENTATIVE FLY PROGRAMS: This product may be used as part of a preventative program or in anticipation of a fly problem associated with an event. Event examples include weddings, picnics, birthday parties, family reunions, graduation parties, etc. Apply inside all garbage receptacles, underneath garbage lids inside recycling bins or receptacles, and other labeled areas that will help prevent flies from being a nuisance.

LEED (Leadership in Energy and Environmental Design) Buildings or GreenPro Programs: Apply inside of sealable containers including mouse stations, fly bait stations or handmade containers with access for the flies. Flies must be active within the building for this application. Do not use as a preventative control product.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry area away from heat or open flame and inaccessible to children.

PESTICIDE DISPOSAL: Wastes resulting from use of this product may be disposed of on site, in accordance with the label directions, or at an approved waste disposal facility.

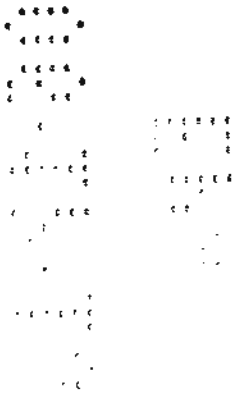
CONTAINER HANDLING & DISPOSAL: Do not puncture or incinerate! **If empty:** Place in trash or offer for recycling, if available. **If partly filled:** Call your local solid waste agency for disposal instructions.

Contains no CFCs or other ozone depleting substances. Federal regulations prohibit CFC propellants in aerosols.

CONDITIONS OF SALE AND WARRANTY

Follow the **Directions for Use**. It is impossible to eliminate all risks inherently associated with use of this product, and therefore all such risk shall be assumed by the Buyer. Whitmire warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to in the **Directions for Use**, subject to the inherent risks, referred to above. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW: (A) WHITMIRE MAKES NO OTHER WARRANTIES EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY, (B) BUYER'S EXCLUSIVE REMEDY AND WHITMIRE'S AND SELLER'S EXCLUSIVE LIABILITY, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, OR OTHERWISE, SHALL BE LIMITED TO REPAYMENT OF THE PURCHASE PRICE OF THE PRODUCT, AND (C) WHITMIRE AND THE SELLER DISCLAIM ANY LIABILITY FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. Whitmire and the Seller offer this product, and the Buyer accepts it, subject to these **Conditions of Sale and Warranty** which may be varied only by agreement in writing signed by a duly authorized representative of Whitmire.

Manufactured for:
Whitmire Micro-Gen Research Laboratories, Inc.®
by BASF Corporation
3568 Tree Court Industrial Blvd.
St. Louis MO 63122-6682
Questions? Call 1-800-777-8570



Inert ingredient information may be entitled to confidential treatment
Product ingredient source information may be entitled to confidential treatment

CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC)
REQUEST FORM

CR# _____

REQUESTOR NAME: Gene Benbow			Request date: 10-5-18
Tel: 347-0235	ORG.: RD	CUBE: 7234	MAIL CODE:

CSF ATTACHED:
[x] YES If CSF is attached complete Item A and the chemical name in item C.
[ ] NO If CSF is not attached complete Item A through C.

fixed [redacted] supplier to clarify source is same as [redacted] source (so no data comp issues) Ranks!

A. INFORMATION REQUIRED:
Check Applicable Category
[ ] Provide PCC and Tolerance Exemption Status For Food-Use Inert ingredient (s).
[ ] Provide PCC for Non-Food Use inert Ingredient (s).
[ ] Provide PCC for Active Ingredient (s).
[ ] Provide PCC for Dye.
[ ] Determine if Fragrance is Acceptable for Use In Formulation.
[ ] *Other (Describe):* _____

B. PESTICIDE PRODUCT INFORMATION:

EPA Reg. No/File Symbol: 499-568	Product Name: PT Alpine Preserved Fly Bait
Registrant: BASF	Food-Use Pesticide: [ ] Yes [x] No
Percent in Formulation (For Fragrance /Dyes)	

C. INGREDIENT INFORMATION: inert clearance at now?

Ingredient No.1

Chem. Name: [redacted]	INFORMATION REPORTED: PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.2:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

OK per D. Deschamps 10.9.18

Ingredient No.3

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Ingredient No.4:

Chem. Name:	PCC:
Trade Name:	TOL. STATUS:
CAS Reg. No.:	OTHER INF.:

Completed By: H. Deschamps
Date Completed: 10-9-18

new pcc form 3485919

Inert ingredient information may be entitled to confidential treatment

INERT INGREDIENT STATUS FORM

Reviewer Name: Alganesh Debesai			Request date: 1/24/2018
Tel: 703-308-8353	RD/IIAB	CUBE: S-7954	

A. COMMENTS:

See under Ingredient No. 1 for details.

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: EPA Reg. No/File Symbol: 499-568	Date on CSF: 11/20/2017	Food-Use Pesticide: [ ] Yes [X]No
Product Name: PT Alpine Pressurized Fly Bait	Formulation: BASIC	

C. INGREDIENT INFORMATION:

Ingredient No.1	Tolerance Exemption(s)[1] 910	920	930	940	950	960
Chem. Name: [redacted]						
Trade Name:						
CAS Reg. No.: [redacted]						
Comments: [redacted]						

[redacted]

old one for reference

— Gene

Completed By: A. Dobosen Date Completed: 2-6-18

[1]*Language from the Code of Federal Regulations (40 CFR 180, subpart D):*
40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

Pages 211-224 - *Confidential Statements of Formula may be entitled to confidential treatment*